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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD., Plaintiffs, v. CIPLA LTD., AUROBINDO PHARMA LLC, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC, Defendants.	:	Consolidated Civil Action No. 20-10172 (MCA)(MAH) CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

REPLY REPORT OF DR. DAVID LEWIS, PH.D.
AS TO DEFENDANT CIPLA LTD.

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I. Introduction, Qualifications, Compensation, and Prior Testimony

1. My name is David Lewis, and I am Director of Oz-UK Ltd. ("Oz-UK") and 3DI Solutions Ltd. ("3DI Solutions"). I set forth my qualifications, compensation, and prior testimony in my Opening Report as to Cipla. My qualifications, compensation, and prior testimony have not changed since that time.

2. I have provided in this matter Opening Reports Concerning Infringement with respect to each of Defendants Cipla and Aurobindo, dated April 29, 2022, in both cases. I refer to my Opening Report Concerning Infringement as to Defendant Cipla herein as my "Opening Report." I have also submitted a Rebuttal Report, dated June 14, 2022. I refer to that report herein as my "Rebuttal Report." I maintain the opinions I offered in each of those reports, and I incorporate them fully as though set forth herein. In this report, I respond to Mr. Gregor Anderson's opinions as provided in his Rebuttal Reports, dated June 14, 2022 ("Anderson Rebuttal Rep."). I also respond to Mr. Anderson's opinions regarding objective indicia of non-obviousness set forth in his Opening Report, dated April 29, 2022 ("Anderson Opening Rep.").

3. In forming my opinions, I have considered the materials cited in this report and materials cited in my Opening Report and my Rebuttal Report. I have also considered the Asserted Patents (as defined below), the Asserted Patents' file histories, Mr. Anderson's reports described in the previous paragraph (and the materials cited in them), Defendants' non-infringement contentions (and the materials cited in them); as well as my education, training, and experience. In addition to the opinions and bases set forth in this report, my testimony may include responses to facts, arguments, allegations, or references raised by Defendants or their experts in this litigation. I reserve the right to supplement my opinions if additional information is provided to me or if additional research leads me to conclude that supplementation is necessary.

II. Legal Standards

A. Person of Ordinary Skill in the Art

4. I have been informed that a POSA is a hypothetical person who may possess the skills, education, and experience of multiple individuals working together as a team. I have been informed that factors for determining the level of ordinary skill in the art may include one or more of the following: (1) the educational level of the inventor; (2) the type of problems encountered in the art; (3) prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the relevant technology; and (6) the educational level of workers active in the field.

5. In my opinion, the POSA for the Asserted Claims as of the priority dates would have had the skills, education, and expertise of a team of individuals working together to research, develop, and manufacture an inhalation aerosol product with a dose counter. Such a team would have included one or more individuals with master's degrees in mechanical engineering, design engineering, or related fields, with at least two years of post-graduate experience in developing inhalation aerosol products, or bachelor's degrees in similar fields of study, with a commensurate increase in their years of postgraduate experience. Such a team also would have been familiar with a variety of issues relevant to researching, developing, and manufacturing inhalation aerosol products with dose counters. The team also would have had access to an individual with a medical degree and experience in treating patients with inhalation aerosol devices.

6. Mr. Anderson opines that as of May 18, 2010, the POSA for the Asserted Claims would be a person with a bachelor's degree in pharmaceutical science or a related discipline, and at least 2-3 years of product development experience with design and manufacture of metered dose inhalers. Alternatively, Mr. Anderson opines that the POSA would have a master's degree

or Ph.D. in pharmaceutical science, mechanical or medical device engineering, or a related discipline, and at least 1-2 years of product development experience with metered dose inhalers. Mr. Anderson also opines that a POSA may have also worked as part of a multi-disciplinary team of scientists in pursuit of developing a pharmaceutical product and drawn upon not only his or her own skills, but also consulted with others of the team having specialized skills. *See, e.g.*, Anderson Opening Rep. ¶ 58.

7. It is unclear to me how Mr. Anderson derived that definition of the POSA, and I disagree with it to the extent that it conflicts with my own. Nevertheless, my opinions would not change if I were to assume, contrary to my opinion, that Mr. Anderson's definition is correct.

8. In his Rebuttal Report, Mr. Anderson offers the opinion that the POSA would not include a physician. Specifically, Mr. Anderson states: "In my experience designing inhalers, a physician might help identify the need for an inhaler and the condition it would treat, but a physician would not design the final product, i.e., the inhaler. In my experience, the final product would be designed by an engineer or scientist. At most, the physician will then verify and validate the needs that the physician identified." Anderson Rebuttal Rep. on Secondary Considerations ¶ 20.

9. Although, as stated above, my opinions would not change if I were to assume that Mr. Anderson's definition is correct, I disagree that the POSA would not include a physician. In my experience in designing inhalation aerosol devices, I and others in the field frequently work with physicians even though they are not "engineers." This is because physicians, unlike engineers or other scientists frequently have specialized knowledge about the actual needs that physicians and patients have with respect to the devices that they develop. Mr. Anderson's purported experience conflicts with mine on this issue, and I disagree with his opinion.

10. I reserve the right to supplement my opinions in the event that the parties present additional argument or evidence relevant to this issue.

B. Claim Construction

11. I have been informed that claim construction refers to the process in which the Court determines the legal meaning of a patent's claims. I have been informed that a patent's claims should be construed according to their ordinary and customary meaning in view of the patent's specification and prosecution history, unless the patent defines a claim term, in which case that definition should be applied.

12. I have been informed that the parties have agreed to the following claim constructions. I have applied those constructions in forming my opinions.

No.	Term	Agreed-Upon Construction
1	"canister housing" '289 Patent, claim 1 '587 Patent, claims 1, 12, and 13	"the portion of the inhaler body that is arranged to retain a medicament canister"
2	"inside surface" '289 Patent, claim 4 '587 Patent, claims 4 and 17	"an interior surface"
3	"body" '156 Patent, claim 1	"the body of the inhaler"
4	"associated with" '156 Patent, claim 1	"related to"
5	"canister support formation" '289 Patent, claims 1, 4 '587 Patent, claims 1, 4, 11-13, 15	"a formation arranged to reduce canister rocking"

6	"actuator" '156 Patent, claims 1, 2, 12	"A structure within the dose counter that can be moved by the canister, is moveable relative to other components of the dose counter, and effectuates movement of at least one additional dose counter component."
7	"actuator pawl arranged to engage with a first tooth of the ratchet wheel" '156 Patent, claim 1	"a pawl that is a part of the actuator of the dose counter that is arranged to engage with a tooth of the ratchet wheel."
8	"wall surfaces separating the canister receiving portion and the counter chamber" '156 Patent, claim 1	"wall surfaces of the inhaler body which are substantially perpendicular to the direction of canister movement and which divide the canister-receiving portion and counter chamber"
9	"regulator" '808 Patent, claims 1, 27	"a structure of the dose counter that modulates motion of the counter display"
10	"regulate motion of the counter display" '808 Patent, claim 1	"modulate motion of the counter display"
11	"ratchet wheel" '156 Patent, claims 1, 9, 12	"a wheel having a plurality of circumferentially spaced teeth arranged to engage with a pawl"
12	"first direction" '808 Patent, claim 1	"single direction at a time"
13	"main surface of the inner wall" '289 Patent, claim 1 '587 Patent, claim 1, 12, 13	"inside surface of the vertical cylindrical portion of the inhaler body, where vertical means substantially parallel to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament"
14	"inner wall through which a portion of the actuation member extends"	"an internal wall of the inhaler body that is horizontal, through which a portion of the actuation member extends, where horizontal means substantially perpendicular to the primary

	'289 Patent, claim 3 '587 Patent, claims 3, 13	direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament"
15	"inner wall" '289 Patent, claims 1, 4 '587 Patent, claims 1, 4, 12, 13, 15, 21, 22	"an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body"
16	"protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler" '587 Patent, claim 1	"guards against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter's actuator enough to cause unwanted incrementing (or decrementing) of the dose counter"

Joint Claim Construction Chart 3-5.

13. I have been informed that the parties dispute the meaning of the following claim terms and have proposed competing constructions. I have been informed that the Court has yet to rule on these disputes. Accordingly, I have applied both parties' constructions in forming my opinions. In my opinion, and as explained in this report, Defendants both infringe each of the Asserted Claims under either side's proposed constructions.

No.	**Term**	**Plaintiffs' Construction**	**Defendants' Construction**
1	"actuation member" '289 Patent, claims 1, 3 '587 Patent, claims 1, 3, 11, 12, 13 '156 Patent, claims 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a component of the dose counter's actuator that transmits motion from the canister to the actuator"	"pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"

No.	Term	Plaintiffs' Construction	Defendants' Construction
2	"[lying or lie] in a common plane coincident with the longitudinal axis X" '289 Patent, claim 1 '587 Patent, claims 1, 12, 21, 22	Plain and ordinary meaning in view of the claims, specification, and prosecution history. Features lie on a common plane coincident with the longitudinal axis X if it is possible to draw a straight line connecting those features that passes through the center of the stem block.	"aligned in a single plane such that a straight line can be drawn though the center of the central outlet port, a canister support formation located directly adjacent to the actuation member, and the actuation member"
3	"positioned at opposite ends of the inside surface of the main body to face each other" '289 Patent, claim 7 '587 Patent, claims 7, 18	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other"	"positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail"
4	"step[(s)] formed thereon" '289 Patent, claims 5, 8 '587 Patent, claims 5, 8, 16, 19	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a location of changing width dimension thereon"	"A stepwise increase in the extent to which the support rail extends inwardly"
5	"first reset position" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is	"configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel"

No.	Term	Plaintiffs' Construction	Defendants' Construction
		before the canister fire configuration"	
6	"canister fire sequence" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament"	"process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the start configuration to the reset configuration, to the [fire configuration as, to the count configuration, before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel."
7	"canister fire configuration" '156 Patent, claims 1, 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a configuration of the dose counter in which the medicament canister fires medicament"	"configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected"
8	"count configuration" '156 Patent, claims 1, 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a configuration of the dose counter whereby the dosage indicator has indicated a count"	"configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose counter has counted one dose"

No.	Term	Plaintiffs' Construction	Defendants' Construction
9	"datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister"	"plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet"
10	"the body" '156 Patent, claim 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "inhaler body" - '156 Patent, 22:64, 67 "dose counter body" - '156 Patent, 22:66	This term is indefinite.
11	"counter display arranged to indicate dosage information" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a component of the dose counter that displays information regarding the number of doses remaining"	"structure displaying the number of doses remaining"
12	"first station" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a first region"	"first structure on which the counter is located"
13	"second station" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and	"second structure, separate from the first structure, to

No.	Term	Plaintiffs' Construction	Defendants' Construction
		prosecution history. "a second region"	which the counter display is moved"
14	"aperture" '289 Patent, claim 3 '587 Patent, claims 3, 13, 20-22	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "an opening or open space: hole"	"hole"
15	"separate counter chamber" '156 Patent, claim 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a separate chamber of the inhaler in which the dose counter is located"	"discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located"
16	"count pawl" '156 Patent, claims 1, 9	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the rachet wheel"	"a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel"

See Joint Claim Construction Chart 6-10.

14. I reserve the right to supplement my opinions in the event that the Court construes these terms or the parties present additional arguments or evidence relevant to these issues.

C. Infringement

15. I have been informed that a party infringes a patent claim if it commercially makes, uses, offers to sell, or sells any patented invention, within the United States or imports

into the United States any patented invention during the term of the patent. I have been informed that a party also infringes a patent claim if it files with the U.S. Food & Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") for a drug claimed in a patent or the use of which is claimed in a patent.

16. I have been informed that a party may infringe a claim literally or under the doctrine of equivalents. I have been informed that even if a party does not literally infringe a claim, it infringes the claim under the doctrine of equivalents if (1) the differences between each claim limitation and the accused equivalent are insubstantial (the "insubstantial differences test") or (2) each claim limitation and the accused equivalent performs substantially the same function in substantially the same way to obtain the same result (the "function-way-result test"). I have been informed that infringement under the doctrine of equivalents is assessed on a claim limitation-by-limitation basis. I have been informed that Plaintiffs bear the burden to prove infringement by a preponderance of the evidence, meaning that a factual proposition is more likely than not. I have applied the above standards in forming my opinions.

17. I have been informed that, in certain circumstances, application of the doctrine of equivalents may be limited if (1) application of the doctrine to the asserted equivalent would encompass or "ensnare" the prior art or (2) by the doctrine of prosecution history estoppel. I have been informed that whether application of the doctrine encompasses or ensnares the prior art depends on an assessment of whether the prior art anticipates or renders obvious the scope of asserted equivalents. I have been informed that prosecution history estoppel may be amendment-based or argument-based.

18. I have been informed that amendment-based prosecution history estoppel generally requires an analysis of the following factors: (1) whether there was a narrowing

amendment during prosecution that surrendered subject matter; (2) whether that narrowing amendment was made for reasons related to patentability; and (3) whether the asserted equivalent is within the scope of the surrendered subject matter, taking into account the presumption of total surrender for the limitation. Conversely, I have been informed that amendment-based prosecution history estoppel does not apply if (a) the equivalent was unforeseeable at the time of the application; (b) the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question; or (c) other reasons suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. I have been informed that argument-based prosecution history estoppel applies when an applicant clearly and unmistakably disclaims the scope of the asserted equivalents.

19. In addition to these issues, certain of Mr. Anderson's opinions refer to "vitiation." I have been informed that vitiation is not a separate exception to the doctrine of equivalents, but rather a legal determination that no reasonable factfinder could find two elements to be equivalent. I have been informed that the insubstantial differences and function-way-result tests are proper inquiries for determining equivalency in such situations. Accordingly, I have applied these tests in responding to Mr. Anderson's opinions regarding "vitiation."

D. Non-Obviousness

20. As I explain in my Opening Report, I have been informed that a patent claim is invalid for obviousness if the differences between the invention it claims and the prior art are such that the invention as a whole would have been obvious to the POSA at the time the invention was made. I have been informed that analysis of whether a claim would have been obvious depends on (a) the scope and content of the prior art, (b) the differences between the claimed invention and the prior art, (c) the level of ordinary skill in the art, and (d) any secondary considerations of non-obviousness. I have been informed that the use of hindsight must be

avoided because the obviousness of an invention is evaluated from the perspective of the POSA at the time the invention was made. Thus, in conducting an obviousness inquiry, one must be aware of the distortion caused by hindsight bias and must be cautious to avoid reading into the prior art the teachings of the claimed invention at issue.

21. I have been informed that a proper obviousness analysis involves an evaluation of any secondary considerations of non-obviousness, also referred to as "objective indicia of non-obviousness." I have been informed that commonly recognized objective indicia include, among others, evidence of long-felt but unsolved needs, failure of others, industry acceptance, and praise. I have been informed that the consideration of such objective indicia guards against hindsight bias and that, in appropriate circumstances, evidence of objective indicia may be determinative of the ultimate question of obviousness. I have been informed that any objective indicia must have a sufficient nexus to the claimed invention(s); that is, the objective indicia must sufficiently relate to the novel aspects of those invention(s).

III. Summary of Opinions

22. The following paragraphs summarize some of my opinions in this matter at a high level. This summary is not meant to limit the opinions expressed below in greater detail, but instead to provide a general overview of the subject matter of my testimony.

23. For my Opening Report, I was asked to provide an opinion regarding whether Cipla infringes the Asserted Claims. In this report, I have been asked to respond to Mr. Anderson's opinions that Cipla does not infringe the Asserted Claims. I have also been asked to respond to Mr. Anderson's opinions regarding objective indicia of non-obviousness.

24. In my opinion, Cipla infringes each of the Asserted Claims. As I explain below in greater detail, Cipla's ANDA Product satisfies each of the limitations of the Asserted Claims, including the limitations recited in the claims from which they depend. To the extent that

Cipla's ANDA Product does not literally satisfy each of those limitations, Cipla's ANDA Product satisfies those limitations under the doctrine of equivalents both because Cipla's ANDA Product has one or more features that are insubstantially different from the limitations in question and because those features perform substantially the same function in substantially the same way to obtain the same result as those limitations. Mr. Anderson's contrary opinions do not demonstrate otherwise.

25. In my opinion, the inventions recited in the Asserted Claims, including as embodied in Qvar® HFA and ProAir® HFA are associated with various objective indicia of non-obviousness, including: (1) the long-felt, unmet needs identified in my Opening Report; (2) the failure of others to satisfy those needs; (3) industry acceptance; (4) praise; and (5) copying. In my opinion, each of these objective indicia, alone and in combination with one or more other objective indicia, provides evidence that the inventions recited in the Asserted Claims would not have been obvious. Mr. Anderson's contrary opinions do not demonstrate otherwise.

IV. Mr. Anderson's "Background of the Relevant Technology," "Summary of Cipla's ANDA Product," and "Summary of the Asserted Patents"

26. In his Rebuttal Report, Mr. Anderson sets forth several sections that purport to describe the "Background of the Relevant Technology," "Summary of Cipla's ANDA Product," and "Summary of the Asserted Patents." In my Opening and Rebuttal Reports, I include several sections addressing these each of these issues, *see, e.g.*, Lewis Opening Rep. §§ II-IV, Lewis Rebuttal Rep. §§ IV-V, and I include further analysis of these issues throughout. I incorporate my own analysis of these issues as through fully set forth herein.

27. For the avoidance of doubt, I disagree with Mr. Anderson's statements in these sections to the extent that they conflict with my opinions or my conclusions regarding the issues

addressed in my reports. To the extent that Mr. Anderson relies on those statements to support his opinions, I address those statements in the context of the concrete issues to which he attaches them.

V. Cipla's ANDA Product Infringes the Asserted Patents

A. Cipla's ANDA Product Infringes the "Common Plane Patents"

1. Cipla's ANDA Product Infringes the '289 Patent

a. Claim 1

28. Asserted Claim 1 of the '289 Patent is set forth below:

> 1. An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

'289 Patent, Claim 1.

29. As I explained in my Opening Report, ¶¶ 54-118, it is my opinion that Cipla's ANDA Product satisfies every limitation of Asserted Claim 1 of the '289 Patent. I incorporate by reference that analysis here as though fully set forth herein, and I do not repeat it solely for the sake of brevity. In this report, I respond to Mr. Anderson's arguments as set forth in his Rebuttal Report dated June 14, 2022 that Cipla's ANDA Product does not meet particular limitations of Asserted Claim 1 of the '289 Patent.

30. Mr. Anderson opines that Cipla's ANDA Product does not meet two limitations of Asserted Claim 1 of the '289 Patent, which he refers to as Limitation 1C ("a dose counter

having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister") and Limitation 1E ("wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port"). I do not understand Mr. Anderson to dispute that Cipla's ANDA Product satisfies all other limitations of Asserted Claim 1. As I explain below, I disagree with Mr. Anderson's opinion that Cipla's ANDA Product does not satisfy Limitations 1C and 1E of Asserted Claim 1 of the '289 Patent.

1) Cipla's ANDA Product Comprises "A Dose Counter Having An Actuation Member Having At Least a Portion Thereof Located in the Canister Housing for Operation by Movement of the Medicament Canister" (Limitation 1C)

31. Cipla's ANDA Product contains a "a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister," which Mr. Anderson refers to as "Limitation 1C."

32. I understand Teva and Defendants disagree regarding the appropriate construction of the term "actuation member," and that the Court has not yet resolved their dispute. The two competing constructions are reflected below.

Term	**Teva's Construction**	**Defendants' Construction**
"actuation member" '289 Patent, claims 1, 3 '587 Patent, claims 1, 3, 11, 12, 13 '156 Patent, claims 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a component of the dose counter's actuator that transmits motion from the canister to the actuator"	"pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"

33. I do not offer any opinion regarding which of the two proposed constructions is correct. However, it is my opinion that Cipla's ANDA Product satisfies Limitation 1C under

either construction of the term "actuation member." I explain this opinion in more detail below.

a) Teva's Construction

34. As I explained in my Opening Report, ¶¶ 72-87, Cipla's ANDA Product contains "a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister," where "actuation member" is construed to mean "a component of the dose counter's actuator that transmits motion from the canister to the actuator." Lewis Opening Rep. ¶¶ 76, 81.

35. In my opinion, Cipla's ANDA Product literally satisfies this limitation under Teva's proposed construction. Cipla's ANDA Product contains an indexer with five castellations. These castellations comprise an "actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."

36. Mr. Anderson suggests that "all five castellations cannot be the claimed 'actuation member' because all five castellations (as a group) do [not] lie in the claimed 'common plane.'" Anderson Rebuttal Rep. ¶ 55. I disagree with Mr. Anderson's characterization of my opinion. It is my opinion that each of the castellations individually comprises an actuation member—that is, Cipla's ANDA Product comprises *five* actuation members.

37. Mr. Anderson also asserts that "a single castellation [cannot] be [an] 'actuation member'" because such a theory "ignores the actuation interaction between the dose counter and the canister." Anderson Rebuttal Rep. ¶ 56. He asserts that:

> The five castellations on the dose counter are arranged at the same height above the lid of the dose counter. Likewise, the canister ferrule that interacts with the castellation is a flat surface. Thus, when the canister is pressed down, it will necessarily contact all the castellations. As discussed in more detail below, it is not possible to rock the canister in an amount sufficient to cause it to contact a single castellation. This too makes it impossible for any single castellation to be the claimed actuation member because it will not perform the functional aspect of Teva or Defendants' proposed construction.

Anderson Rebuttal Rep. ¶ 56. I disagree with Mr. Anderson's opinion for several reasons.

38. Mr. Anderson's statements above appear to assume, incorrectly, that a component of the dose counter can only be an actuation member if it constitutes the entirety of the surface contacted by the canister. I see nothing in the language of Asserted Claim 1 or Teva's construction of actuation member (or Defendants' construction of actuation member, for that matter) that is consistent with Mr. Anderson's interpretation. Under Teva's construction, an actuation member is "a component of the dose counter's actuator that transmits motion from the canister to the actuator." Each castellation satisfies this requirement. Mr. Anderson acknowledges that each castellation can contact the canister, *see* Anderson Rebuttal Rep. ¶ 56, and each castellation is attached to/molded from the same piece of plastic as the indexer (the "actuator" of Cipla's ANDA Product), meaning that downward motion of the castellation causes downward motion of the indexer. Thus, each castellation is "a component of the dose counter's actuator that transmits motion from the canister to the actuator."

39. Mr. Anderson also asserts that I "present[] no analysis demonstrating that a single castellation, by itself, transmits motion from the canister to the actuator as is required under Teva's proposed construction of 'actuation member.'" Anderson Rebuttal Rep. ¶ 56. To the extent Mr. Anderson suggests otherwise, I do not see any basis in the claim or Teva's construction for requiring that, in order to be an actuation member, a component of the dose counter need be the *only* feature of the dose counter that interacts with the canister and transmits motion from the canister to the actuator. (In other words, I see no requirement in Asserted Claim 1 that prohibits the presence of multiple actuation members.) Certainly, each castellation individually "transmits motion from the canister to the actuator." No experimental data is needed to demonstrate this fact—each castellation is physically connected to the actuator and

molded from the same piece of plastic as the actuator, and thus downward movement of a castellation necessarily results in downward movement of the actuator. Notwithstanding this commonsense conclusion, in response to Mr. Anderson's arguments I have demonstrated that pressing downward on one castellation of Cipla's ANDA Product individually (in a manner that does not apply force to any other castellation) can transmit motion to the actuator sufficient to record a count. I recorded a video demonstrating this fact with respect to one castellation, and have confirmed that it is equally true of all five castellations. *See* TEVADOC-00000845. [redacted] To be clear, I offer no opinion as to whether such a result is required by the claims; I recorded these videos solely to demonstrate that Mr. Anderson's statements were not accurate.

40. In addition, Mr. Anderson's assertion that the canister will always interact equally with all the castellations of Cipla's ANDA Product ignores the realities of manufacturing. Even if the five castellations of the indexer are designed to be located the same distance below the medication canister before the canister is depressed, variations in manufacturing of the indexer (including its castellations), as well as variations in the valve stem block, valve, and canister, mean that this goal will seldom be achieved precisely. In practice, the canister may sit at an angle in the valve stem block, or its drive surface may not be perfectly flat and perpendicular to the valve's axis of movement, or one castellation may simply be slightly taller than the others—each of these conditions caused by manufacturing tolerances (and tolerance stacking) can and will cause the medication canister to interact first with a single castellation. And as I have described above, even if no other castellations were present, the canister's interaction with a single castellation would be sufficient to increment the dose counter.

b) Defendants' Construction

41. In the event the Court adopts Defendants' construction of "actuation member,"

my opinion that Cipla's ANDA Product satisfies Limitation 1C would not change. As I explained in my opening report, Cipla's ANDA Product contains a "a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister," where "actuation member" is construed to mean "pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count." Lewis Opening Rep. ¶¶ 79-87.

42. In my opinion, each of the castellations of Cipla's ANDA Product is a "pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count." Each castellation is a pin in that it is a "slender, elongated structure." Lewis Opening Rep. ¶ 81. Mr. Anderson's opinion to the contrary appears to rely on nothing other than a structure in the '289 Patent that is referred to as an "actuation pin" and that, in his opinion, "is quite different from the castellations of the indexer in Cipla's ANDA Product." Anderson Rebuttal Rep. ¶ 61. I disagree with Mr. Anderson—the particular "actuation pin" depicted in Figure 4A of the '289 Patent is not the only form a "pin" can take. To the contrary, the POSA would understand that the castellations of Cipla's ANDA Product are pins within the plain and ordinary meaning of that term because they are slender, elongated structures.

43. Mr. Anderson again faults my opinion for "provid[ing] no analysis of how pressing down on a single castellation could possibly 'effect movement causing the dose counter to record a count' as is required under Defendants' proposed construction." Anderson Rebuttal Rep. ¶ 66. I disagree that any such "analysis" is necessary, and I plainly stated in my Opening Report that "[e]ach of those actuation members [i.e., castellations] literally qualifies as a pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count." Lewis Opening Rep. ¶ 81. Nevertheless, in direct response to Mr. Anderson's

claim that "it is not possible to press down on a single castellation" to effect a count, I have (as I described above) demonstrated that pressing downward on one castellation of Cipla's ANDA Product individually (in a manner that does not apply force to any other castellation) can transmit motion to the actuator sufficient to record a count. I recorded a video demonstrating this fact with respect to one castellation, and have confirmed that it is equally true of all five castellations. *See* TEVADOC-00000845 (Cipla); [redacted] As I have made clear, I do not believe these videos to be necessary to establish infringement, but I provide it only in response to Mr. Anderson's incorrect statement that individual castellations cannot transmit sufficient motion to cause a count. This result occurred notwithstanding Mr. Anderson's suggestion that it is not possible to "disengage" all five teeth of the units teeth ring from the teeth of the indexer and advance the counter by "pressing down" on only a single castellation. Mr. Anderson is incorrect—each castellation is "arranged to engage with a medicament canister and effect movement causing the dose counter to record a count."

44. To the extent that the castellations of Cipla's ANDA Product do not literally qualify as "pins" within the meaning of Defendants' construction, the castellations of Cipla's ANDA Product nonetheless satisfy Defendants' construction under the doctrine of equivalents.

45. **Insubstantial Differences Test.** The castellations of Cipla's ANDA Product are insubstantially different from the pins of that construction and the pins of the '289 Patent. *See* Lewis Opening Rep. ¶ 85. Indeed, the castellations of Cipla's ANDA Product are slender, elongated structures that transmit motion for the medicament canister to the actuator—whether or not this makes them literal "pins," it does make them insubstantially different from and thus equivalent to the "pin(s)" of Defendants' construction (including the slender, elongated "actuation pin" shown in Figure 4A of the '289 Patent). I have not ignored "the requirement that

the movement be sufficient to record a count," *contra* Anderson Rebuttal Rep. ¶ 69—to the contrary, I stated expressly in my Opening Report that each "actuation member [i.e., castellation] literally qualifies as a pin arranged to engage with a medicament canister *and effect movement causing the dose counter to record a count*." Lewis Opening Rep. ¶ 81. As I have explained repeatedly above, Mr. Anderson is incorrect that a single castellation cannot transmit sufficient motion to record a count. I have (as I described above) confirmed that pressing downward on one castellation of Cipla's ANDA Product individually (in a manner that does not apply force to any other castellation) can transmit motion to the actuator sufficient to record a count. I recorded a video demonstrating this fact with respect to one castellation, and have confirmed that it is equally true of all five castellations. *See* TEVADOC-00000845 (Cipla); [redacted] As I have made clear, I do not believe these videos to be necessary to establish infringement, but I provide it only in response to Mr. Anderson's incorrect statement that individual castellations cannot transmit sufficient motion to cause a count.

46. **Function-Way-Result Test.** Furthermore, each castellation of Cipla's ANDA Product performs substantially the same function in substantially the same way to achieve substantially the same result as the pin(s) of Defendants' construction. As I stated in my Opening Report, "both perform substantially the same function in substantially the same way to obtain the same result. Both perform the function of transmitting motion from the medicament canister to the actuator, by way of providing a slender, elongated structure, to obtain the result of transmitting that motion to other dose counter components." Lewis Opening Rep. ¶ 86.

47. Mr. Anderson asserts that my "'way' is incorrect" and that the correct "way" within the context of the "function, way, result" test is "by contacting the medicament canister in a manner sufficient to transmit the motion of the canister to the dose counter." Anderson

Rebuttal Rep. ¶ 71. I disagree—in my opinion, that is the *function* of the actuation member, not the "way" in which the actuation member performs its function. Regardless, each castellation of Cipla's ANDA Product likewise performs its function in the way Mr. Anderson describes—i.e., each castellation "contact[s] the medicament canister in a manner sufficient to transmit the motion of the canister to the dose counter." Mr. Anderson appears to agree that each castellation can contact the medicament canister. *See* Anderson Rebuttal Rep. ¶ 56. And again, as I verified in response to Mr. Anderson's statement to the contrary, interaction with each individual castellation of Cipla's ANDA Product is independently sufficient to increment the dose counter. *See* TEVADOC-00000845 (Cipla); [redacted]

48. Mr. Anderson also takes issue with my identification of the result of the actuation member's function, calling it "circular and simply a restatement" of the function I identified. Anderson Rebuttal Rep. ¶ 71. Instead, Mr. Anderson asserts, "[t]he result must relate to counting a dose as reflected by Defendants' Proposed Construction. As explained above, pressing on a single castellation does not result in a dose being counted." Anderson Rebuttal Rep. ¶ 71. Again, I disagree—the result of the actuation member's transmission of motion from the canister to the actuator is that the actuator can then cause movement of other dose counter components. Regardless, even if the appropriate analysis under the function, way, result test involves a result "relate[d] to counting a dose" as Mr. Anderson suggests, the castellations of Cipla's ANDA Product achieve that result. *See* TEVADOC-00000845 (Cipla); [redacted] Each castellation is independently capable of incrementing the dose counter—Mr. Anderson is simply incorrect that "pressing on a single castellation does not result in a dose being counted." Anderson Rebuttal Rep. ¶ 71.

49. Accordingly, I disagree with Mr. Anderson's opinions with respect to Limitation

1C. In my opinion, Cipla's ANDA product meets Limitation 1C under Teva's construction and meets Limitation 1C under Defendants' construction (both literally and under the doctrine of equivalents).

2) Cipla's ANDA Product Comprises a "Canister Housing" with a "Longitudinal Axis X Which Passes Through the Center of the Central Outlet Port, the Inner Wall Canister Support Formation, the Actuation Member, and the Central Outlet Port Lying in a Common Plane Coincident with the Longitudinal Axis X" (Limitation 1E)

50. Cipla's ANDA Product contains a "canister housing" with a "a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X." Lewis Opening Rep. ¶¶ 103-18. Mr. Anderson and I refer to this limitation as the "Common Plane Limitation," and Mr. Anderson sometimes also refers to this limitation as "Limitation 1E."

51. I understand Teva and Defendants disagree regarding the appropriate construction of the Common Plane Limitation and that the Court has not yet resolved their dispute. The two competing constructions are reflected below.

Term	**Teva's Construction**	**Defendants' Construction**
"[lying or lie] in a common plane coincident with the longitudinal axis X" '289 Patent, claim 1 '587 Patent, claims 1, 12, 21, 22	Plain and ordinary meaning in view of the claims, specification, and prosecution history. Features lie on a common plane coincident with the longitudinal axis X if it is possible to draw a straight line connecting those features that passes through	"aligned in a single plane such that a straight line can be drawn though the center of the central outlet port, a canister support formation located directly adjacent to the actuation member, and the actuation member"

	the center of the stem block.	

52. I do not offer any opinion regarding which of the two proposed constructions is correct. As I explained in my Opening Report, however, it is my opinion that Cipla's ANDA Product satisfies the Common Plane Limitation/Limitation 1E under either construction. Lewis Opening Rep. ¶¶ 103-18.

53. Mr. Anderson asserts that the purpose of the common plane limitation is to "reduce rocking in the direction of the actuation member." Anderson Rebuttal Rep. ¶ 75. He asserts that I agree with this statement, citing paragraph 114 of my Opening Report. For clarity, I agree that *one* purpose of arranging an inner wall canister support formation in a common plane with the central outlet port and actuation member is to prevent canister rocking relative to the actuation member (whether toward or away from the actuation member). However, as the prosecution history of the '289 Patent makes clear, the arrangement required by the Common Plane Limitation has other purposes—including to "prevent a canister from rocking too much relative to the main body of the inhaler." Lewis Opening Rep. ¶ 107 (citing '289 Prosecution History, Office Action Response 5 (Mar. 7, 2016)). Furthermore, to the extent Mr. Anderson suggests that Asserted Claim 1 of the '289 Patent requires "reduc[ing] rocking in the direction of the actuation member," I disagree—I do not see any such requirement in the language of Asserted Claim 1 of the '289 Patent, nor in either party's construction of the Common Plane Limitation.

54. Mr. Anderson asserts that "[i]n the '289 Patent, the only inner wall canister support formation that can perform" the function of "reduc[ing] rocking in the direction of the actuation member" is the one circled in red in Mr. Anderson's annotated version of Figure 7D of

the ’289 Patent, which I have reproduced below.

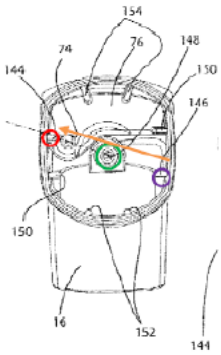


FIG. 7D

Anderson Rebuttal Rep. ¶ 75. I do not agree that the inner wall canister support formation Mr. Anderson has circled in red in the reproduction of Figure 7D above is the only inner wall canister support formation shown in Figure 7D that could prevent canister rocking in the direction of the actuation member. Mr. Anderson has provided no evidence to support this assertion, and indeed I note several other inner wall canister support formations shown in Figure 7D are on the same side of the inhaler body as the actuation member, and thus would appear to reduce the canister’s rocking in the direction of the actuation member even under Mr. Anderson’s limited understanding of how that can be accomplished. I have circled those support rails in blue below. Furthermore, to the extent Mr. Anderson implies that the presence of a support rail on the opposite side of the canister housing from the actuation member at issue could not reduce rocking sufficient to cause a count, he is incorrect. By restricting the freedom of movement of the canister generally, every support rail reduces the magnitude of overall canister rocking (including “rebounds” that might result in the canister bouncing off one side of the inhaler housing and then rocking towards the opposite side).

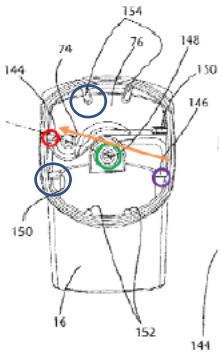


FIG. 7D

However, as I stated above, I do not see that this annotation of Figure 7D bears upon the requirements of Asserted Claim 1 of the '289 Patent, which does not require that inner wall canister support formations be located at positions identical to those shown in Figure 7D of the '289 Patent, nor does it recite a purpose or result that the Common Plane Limitation must achieve. Another purpose of the Common Plane Limitation is to prevent rocking of the canister relative to the main body of the inhaler, and all of the inner wall canister support formations shown in Figure 7D would accomplish this purpose (although again, I see nothing in Asserted Claim 1 or either parties' construction of the Common Plane Limitation that requires such a purpose be achieved).

55. Mr. Anderson also asserts that various statements in the prosecution history of the '289 Patent connecting the Common Plane Limitation to improved dose counter accuracy "hold true only if the canister could be rocked enough to transmit sufficient motion to the actuation member to record a count" because "rocking does not impact accuracy of the dose counter so long as it cannot cause an unintentional count." Anderson Rebuttal Rep. ¶ 76. I disagree with Mr. Anderson that canister rocking cannot affect dose counter accuracy unless the rocking is sufficient to cause a count. In my experience, dose counter inaccuracies can also occur if a

patient moves the medication canister in a manner that fires medication but fails to actuate the dose counter, a likelihood that is increased by "off-axis" actuation of the canister—i.e., canister rocking during patient use. Indeed, in order to respond to Mr. Anderson's argument and demonstrate the factual inaccuracies in his opinion, I removed certain support rails from Cipla's ANDA Product and demonstrated that canister rocking can cause medication to fire without incrementing the dose counter, a situation that introduces dose counter inaccuracies. *See* TEVADOC-00000844 (showing rocking that leads to medication firing but no count in a sample of Cipla's ANDA Product after removing all inner wall canister support formations except for the mounting tabs). I recorded a similar demonstration using Aurobindo's ANDA Product – I again removed all inner wall canister support formations except for the mounting tabs, and rocked the canister in a different direction that caused dose counter inaccuracy in the form of firing but not counting. [redacted]

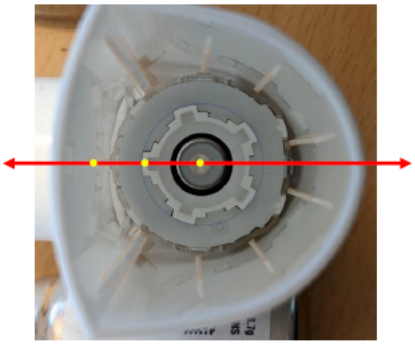
56. Furthermore, to the extent Mr. Anderson is suggesting that Asserted Claim 1 of the '289 Patent requires that the arrangement of the inner wall canister support formation, actuation member, and central outlet port in a common plane must "reduce rocking in the direction of the actuation member" where that rocking would otherwise have been sufficient to cause the dose counter to register an unwanted count, I disagree. I see no such requirement in Asserted Claim 1 of the '289 Patent nor either party's construction.

a) Teva's Construction

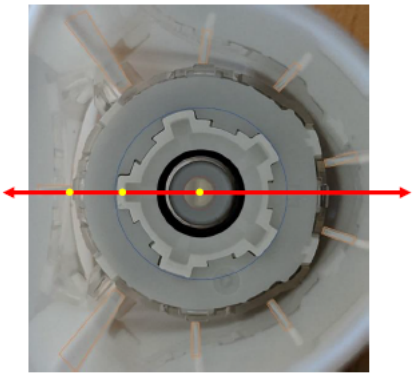
57. Cipla's ANDA Product satisfies the Common Plane Limitation because it contains an inner wall canister support formation that lies in a common plane with the center of the central outlet port and an actuation member (castellation). Lewis Opening Rep. ¶¶ 105-11.

58. In paragraph 110 of my Opening Report, I illustrated one such common plane, as follows:

Cipla's ANDA Product, 40 mcg

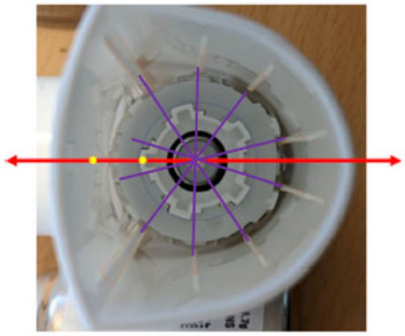


Cipla's ANDA Product, 80 mcg



I also stated that "it is possible to construct multiple common planes passing through the relevant components of Cipla's ANDA Product." Lewis Opening Rep. ¶ 110. Mr. Anderson does not disagree that the red line I have drawn above depicts a configuration of an inner wall canister support formation, actuation member, and central outlet port in Cipla's ANDA Product that satisfies the Common Plane Limitation. However, he states that no other Common Planes exist, because "the other planes passing through a rib and the central outlet port fail to intersect a castellation," a point he attempts to illustrate with the figure below:

Cipla's ANDA Product, 40 mcg



Anderson Rebuttal Rep. ¶ 79. Mr. Anderson is incorrect. It is not accurate to say that "there are no other planes that could be drawn that pass through each of a rib, a castellation, and the central outlet port." Anderson Rebuttal Rep. ¶ 79. The purple lines Mr. Anderson has drawn in the image above do not reflect every possible line that connects the central outlet port, an inner wall canister support formation, and an actuation member/castellation. Certainly, these lines do not reflect all possible angles at which such lines could be drawn and still pass through a castellation, a support rail, and the central outlet port.

59. Mr. Anderson also asserts that the Common Plane I illustrated in Paragraph 110 of my Opening Report is somehow invalid, because, he states, I have not demonstrated that the castellation (i.e., actuation member) that lies in this particular common plane satisfies all the limitations of Asserted Claim 1 of the '289 Patent, nor have I demonstrated that this castellation "could possibly perform the claimed function of the common plane limitation under either party's construction," and therefore I have not demonstrated that "this single castellation is the claimed 'actuation member.'" Anderson Rebuttal Rep. ¶ 81. I disagree with Mr. Anderson. As I have explained above, each castellation of Cipla's ANDA Product is an actuation member within the meaning of both Teva's and Defendants' constructions—it transmits motion from the canister to the actuator, and can transmit sufficient motion to cause the dose counter to count.

See TEVADOC-00000845 (Cipla); [redacted]

60. Mr. Anderson is also incorrect that "pressing down on a single castellation is not even possible with a medicament canister inserted into the device." Anderson Rebuttal Rep. ¶ 81. Mr. Anderson again assumes that two dimensional drawings behave perfectly and inflexibly in the real world. That is not the case—the indexer may be intended to be planar and perpendicular to the canister's direction of movement, but the canister can rock and the indexer can tilt, causing the canister to interact first with a leading castellation that transfers force to the rest of the actuator. Indeed, I have recorded videos demonstrating the canister's interaction with a single castellation preferentially and the ensuing tilt of the indexer. *See* TEVADOC-00000846 (filmed using Cipla's ANDA Product with all inner wall canister support formations still present, but a portion of the housing removed for visibility); [redacted] Regardless, Asserted Claim 1 does not exclude the possibility of multiple actuation members—it merely requires an inhaler that has at least one actuation member in a common plane with an inner wall canister support formation and the center of the central outlet port. As I have illustrated, the castellation closest to the mouthpiece (the "front") lies in a common plane with an inner wall canister support formation and the center of the central outlet port. And, as I have demonstrated, there are other pairs of castellations and inner wall canister support formations that also lie in a common plane with the central outlet port.

61. Mr. Anderson also faults my analysis for "fail[ing] to demonstrate that the rib [I] identify . . . does anything to prevent rocking." Anderson Rebuttal Rep. ¶ 82. I disagree that such a demonstration is required to establish infringement of Asserted Claim 1 of the '289 Patent, because neither Asserted Claim 1 of the '289 Patent nor either party's construction of the

Common Plane Limitation requires the prevention of rocking. Even setting that point of disagreement aside, I also disagree that any analysis would be necessary to establish that the rib closest to the mouthpiece of the device limits rocking—by extending into the cavity of the inhaler, it necessarily limits the canister's freedom of movement in the direction of the front of the device, as I demonstrated in my opening report. *See, e.g.*, Lewis Opening Rep. ¶ 181 (showing that the maximum front to back movement of the canister increased upon removal of the ribs). I note that elsewhere in his Rebuttal Report, Mr. Anderson expresses concern that these measurements because "[t]o the extent Dr. Lewis removed the mounting tabs, his test would be biased towards allowing for increased rocking and would not reliably test the claim limitation." Anderson Rebuttal Rep. ¶¶ 133-34. I disagree that removal of the mounting tabs (or more than one inner wall canister support formation generally) renders the test biased or otherwise faulty. However, I note that I did *not* in fact remove the mounting tabs in performing this experiment. An image depicting the 80 mg Cipla ANDA Product Sample after I had altered it to perform the experiment I reported in paragraph 181 of my Opening Report is shown below:

62. Mr. Anderson also argues that I "fail[] to demonstrate that but for the identified rib, the canister could rock enough to cause the dose counter to record an unintentional count" and I therefore "fail[] to analyze whether the rib performs the function identified by the applicant during prosecution of the '289 patent." Anderson Rebuttal Rep. ¶ 81. I again disagree. Asserted Claim 1 of the '289 Patent contains no such requirement. Furthermore, Mr. Anderson's conclusion that, in the absence of this rib, the canister in Cipla's ANDA Product could not rock sufficiently to record a count is deeply flawed.

63. In forming that flawed opinion, Mr. Anderson calculates the theoretical angle at which the canister would have to be tilted in order to compress the indexer 1.9 mm vertically (the distance Mr. Anderson argues is required to achieve a count). Anderson Rebuttal Rep. ¶ 85. He concludes that the canister housing would prevent rocking to that degree. Anderson Rebuttal Rep. ¶ 85. He is incorrect. Mr. Anderson's theory does not accurately reflect real world experience, as so often is the case in inhaler development. Mr. Anderson assumes that the only manner in which the canister could rock is from a position at which the valve is fully extended or at rest (meaning that the canister is as far away vertically from the castellations as possible). This is not accurate. The canister could be partially depressed before rocking, or could rock and then be partially depressed, which would greatly reduce the degree of rocking required to register a count. In my experience, both scenarios occur in inhaler use (for example, when patients fidget with their inhalers, or when one person assists another in actuating the inhaler). Indeed, in response to Mr. Anderson's assertion that it is not possible for the canister to rock sufficiently to cause the dose counter to record an unwanted count, I recorded myself demonstrating that such rocking is entirely possible. For example, in one sample of Cipla's ANDA Product, I removed all inner wall canister support formations except the mounting tabs. *See* TEVADOC-00000843.

I then rocked the canister towards the mouthpiece (i.e., in the direction of the individual actuation member and (now absent) rib to which Mr. Anderson limits his analysis) and then depressed the canister by sliding it along the inner wall of the inhaler. *See* TEVADOC-00000843. As the video reflects, the dose counter of Cipla's ANDA Product several times recorded a count as a result of such rocking even though medication was not expelled. *See* TEVADOC-00000843. [redacted]

b) Defendants' Construction

64. Mr. Anderson opines that, under Defendants' construction, Cipla's ANDA Product fails to satisfy the Common Plane Limitation for the additional reason that the inner wall canister support formation on which he focuses his analysis is not "directly adjacent to the actuation member." *See, e.g.*, Anderson Rebuttal Rep. ¶ 90. Mr. Anderson is incorrect. For all the reasons I explained in my Opening Report, ¶¶ 112-18, Cipla's ANDA Product satisfies Limitation 1E under the doctrine of equivalents.

65. **Insubstantial Differences Test.** In my opinion, in the event the Court determines Defendants' construction of the Common Plane Limitation is correct, Cipla's ANDA Product satisfies that limitation under the doctrine of equivalents, as I explained in my Opening Report, because Cipla's ANDA Product is configured in a manner insubstantially different from the recited Common Plane Limitation. Lewis Opening Rep. ¶¶ 112-16. Mr. Anderson argues that my opinion "ignores [Teva's] identified purpose for this limitation—preventing rocking that would reduce accuracy" and that, "[i]n effect, [I] opine[] that any set of an inner wall canister support formation, actuation member, and central outlet port that are in a single plane will satisfy the claim." Anderson Rebuttal Rep. ¶ 92. Mr. Anderson is incorrect for several reasons.

66. As is clear from my analysis above, the support rail in Cipla's ANDA Product that is closest to the mouthpiece of the inhaler—and that, according to Mr. Anderson, fails to satisfy Defendants' construction because it is "not directly adjacent" to the nearest actuation member—does indeed prevent canister rocking. This fact is apparent even without testing, because the presence of a rail that extends into the space of the inhaler body necessarily restricts the canister's movement in the direction of that rail, and therefore reduces canister rocking. *See, e.g.*, Lewis Opening Rep. ¶ 181 (showing that support rails reduce, e.g., the front-to-back movement of the canister). The measurements I reported in my Opening Report confirm this fact empirically. *See, e.g.*, Lewis Opening Rep. ¶ 181 (showing that support rails reduce, e.g., the front-to-back movement of the canister). Regardless, and as I have demonstrated in response to Mr. Anderson's inaccurate statements, in the absence of this support rail, the canister is capable of rocking in the direction of that (now absent) rail enough to cause an unwanted count (i.e., a count that occurs when medication is not dispensed). *See* TEVADOC-00000843 (Cipla); [redacted] Such rocking thus reduces counter accuracy—precisely the purpose Mr. Anderson identifies for the Common Plane Limitation.

67. Mr. Anderson goes on to say that "rocking the canister in a direction opposite from the "actuation member" (toward the purple circle [in the image below]) would do nothing to improve accuracy. A rocking in that direction could never cause an unintentional count in the device shown below."

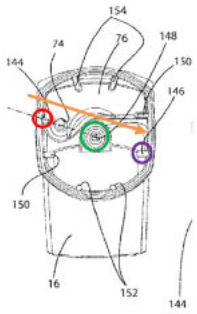


FIG. 7D

Anderson Rebuttal Rep. ¶ 92. Mr. Anderson's two-dimensional drawing with an arrow does not demonstrate what can or cannot happen in a device when used by real-world patients. In addition, Mr. Anderson overlooks that the Asserted Claims of the '289 Patent are not limited to devices that resemble Figure 7D of the '289 Patent. More generally, however, Mr. Anderson is incorrect that the presence of a support rail on the opposite side of the canister housing from the actuation member at issue could not reduce rocking sufficient to cause a count—by restricting the freedom of movement of the canister generally, every support rail reduces the magnitude of overall canister rocking (including "rebounds" that might result in the canister bouncing off one side of the inhaler housing and then rocking towards the opposite side).

68. Furthermore, Mr. Anderson ignores that the stated purpose of the Common Plane Limitation—as Teva explained in the prosecution history—is not just to reduce rocking *in the direction of the actuation member*. Rather, it is to improve the accuracy of the dose counter, including by "prevent[ing] a canister from rocking too much relative to the main body of the inhaler." Lewis Opening Rep. ¶ 107 (citing '289 Prosecution History, Office Action Response 5 (Mar. 7, 2016). Plainly, a support rail does not need to be located on the same side of the canister as an actuation member in order to reduce rocking of the canister relative to the main body of the inhaler. And as I have shown above, rocking also can lead to dose counter

inaccuracy when the canister fires but the dose counter fails to advance. *See, e.g.*, TEVADOC-00000844 (Cipla);[redacted]

69. However, as I have explained above, and as I explain again here, I would disagree with Mr. Anderson's opinion even if I adopted, *arguendo*, his incorrect understanding of the purpose of the Common Plane Limitation. In the absence of the support rail in the "front" of the inhaler, it is indeed possible to rock the canister towards the front (i.e., mouthpiece) of the inhaler in a manner sufficient to cause an unwanted count. *See* TEVADOC-00000843 (Cipla); *see also* TEVADOC-00000840 (Aurobindo). Mr. Anderson's assertion, repeated in paragraph 93 of his rebuttal report, that "the wall of the inhaler body (even without ribs) prevents [canister] rocking to the point of an unintentional count," and thus that removing the inner wall canister support formation nearest the inhaler mouthpiece "does not result in the ability to rock the canister enough to record a counter [*sic*]" is simply incorrect. As I have explained and documented, Mr. Anderson's theoretical calculation, apparently based on images of the inhaler shown in paragraph 84 of his report, does not reflect the reality of inhaler use. I do not understand Mr. Anderson to offer any other basis for disagreement with my theory of infringement under the insubstantial differences test.

70. In paragraph 94 of his rebuttal report, Mr. Anderson misreports my opinion. He states that, in paragraph 115 of my Opening Report, I "opine that '[t]o the extent that Cipla's ANDA Product does not comprise an inner wall canister support formation, the POSA would understand this to be inessential.'" In paragraph 115 of my Opening Report, what I actually state is: "Thus, to the extent that, in certain embodiments, the actuation member is located directly adjacent to the inner wall canister support formation, the POSA would understand this to be an inessential aspect of the inventions as a whole." I do not, by virtue of this statement, concede

that Cipla's ANDA Product does not meet the Common Plane Limitation under Defendants' construction. Rather, it is my opinion that, in the event the Court adopts Defendants' construction of the Common Plane Limitation, Cipla's ANDA Product is configured in a manner that is insubstantially different, because the "directly adjacent" requirement is not essential to achieve the purpose of the Common Plane Limitation.

71. In paragraph 116 of my Opening Report, I mistakenly left out several words from my final sentence—here, I did inadvertently state that "To the extent that Cipla's ANDA Product does not comprise an inner wall canister support formation, the POSA would understand this to be inessential." What I intended to say was "To the extent that Cipla's ANDA Product does not comprise an inner wall canister support formation *located directly adjacent to the actuation member*, the POSA would understand this to be inessential." For clarity, it is my opinion that Cipla's ANDA Product possesses several inner wall canister support formations, and I make this opinion clear throughout my Opening Report. *See, e.g.*, Lewis Opening Rep. ¶¶ 88-96. I do not understand Mr. Anderson to dispute the fact that Cipla's ANDA Product contains several inner wall canister support formations.

72. **Function, way, result test.** As I explained in my Opening Report, Cipla's ANDA Product also satisfies Defendants' construction of the Common Plane Limitation under the doctrine of equivalents as assessed via the function, way, result test. Lewis Opening Rep. ¶¶ 117-18. Cipla's ANDA Product on the one hand, and an inhaler that literally satisfies Defendants' construction of the Common Plane Limitation on the other "[b]oth perform substantially the function of restricting the extent to which the medicament canister can move towards the actuation member, by way of restricting the amount of space that the canister can move in that direction, to obtain the result of reducing rocking in that direction." Lewis Opening

Rep. ¶ 117.

73. Mr. Anderson disagrees with my analysis because (1) he disagrees that a single castellation can serve as an actuation member, and (2) he asserts my "'result' fails to take into account the purpose of reducing the rocking—preventing unintentional counts." Anderson Rebuttal Rep. ¶ 97. I disagree with Mr. Anderson on both points. I have extensively addressed the first above—application of force to a single castellation is capable of causing the dose counter in [redacted] to count. *See* TEVADOC-00000845 (Cipla); [redacted] With respect to the second, Mr. Anderson asserts that "[t]he proper result must relate to preventing unintentional counts or improving the accuracy of the device" and—he repeats—the "rib" closest to the mouthpiece does not improve counter accuracy. Anderson Rebuttal Rep. ¶ 97. Even if I accept Mr. Anderson's characterization of the proper "result" for the "function, way, result" test, I have demonstrated in response that the presence of the rib closest to the inhaler mouthpiece (which lies in a Common Plane with the actuation member closest to the mouthpiece and the center of the central outlet port) does satisfy this result. *See* TEVADOC-00000843 (Cipla); [redacted]

b. Dependent Claims of the '289 Patent

74. Mr. Anderson does not address each Asserted Claim of the '289 Patent individually. Instead, he argues that that Cipla's ANDA Product does not infringe the asserted dependent claims of the '289 Patent because Cipla's ANDA Product does not infringe Asserted Claim 1 of the '289 Patent. As explained in detail above, I disagree with Mr. Anderson's analysis of Asserted Claim 1. For all the reasons outlined above and in my Opening Report, I conclude that Cipla's ANDA Product infringes Asserted Claim 1. Below, I address Mr. Anderson's additional arguments regarding Asserted Claims 3, 5, and 8. Mr. Anderson does not provide additional noninfringement arguments with respect to Asserted Claims 2, 4, 6 or 7

beyond those he provides in the context of Asserted Claim 1.

c. Claim 3

75. Asserted Claim 3 depends from Asserted Claim 1 and recites, "the inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends." As I set forth in my Opening Report, Cipla's ANDA Product infringes Asserted Claim 3. Opening Rep. ¶¶ 126-39.

76. I have been informed that the parties have agreed that the term "inner wall through which a portion of the actuation member extends" should be construed to mean "an internal wall of the inhaler body that is horizontal, through which a portion of the actuation member extends, where horizontal means substantially perpendicular to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament." I have applied this construction throughout my opinions.

77. I have been informed that the parties have proposed different constructions for the term "aperture." I have set forth those competing constructions below:

Term	**Teva's Construction**	**Defendants' Construction**
"aperture"	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "an opening or open space: hole."	"hole"

78. I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla's ANDA Product infringes under either proposed construction.

79. As I explained in my Opening Report, Cipla's ANDA Product infringes Asserted Claim 3 of the '289 Patent. Lewis Opening Rep. ¶¶ 126-39. Mr. Anderson contends that—in

addition to his arguments with respect to Asserted Claim 1, which I have addressed above—Cipla's ANDA Product fails to meet Asserted Claim 3's requirement for "an aperture formed in the inner wall through which the portion of the actuation member extends." Anderson Rebuttal Rep. ¶¶ 103-11. I disagree with Mr. Anderson.

80. Portions of the actuation members of Cipla's ANDA Product extend through a hole (i.e., aperture) in the lid of the dose counter. Lewis Opening Rep. ¶¶ 129-39. To the extent that this arrangement does not literally satisfy Asserted Claim 3's requirements, it does so under the doctrine of equivalents, as I explained in my Opening Report. Lewis Opening Rep. ¶¶ 134-39.

81. **Insubstantial Differences Test.** Mr. Anderson disagrees with my analysis under the insubstantial differences test, because—in his opinion—I have "completely ignore[d] the recitation of the "aperture *formed in the inner wall*" and thus ignored that "[t]he location of the aperture matters. Otherwise, all apertures through which a portion of the dose counter protrudes would be equivalent." Anderson Rebuttal Rep. ¶ 106. I disagree with Mr. Anderson. In fact, the location of the aperture in the dose counter lid of Cipla's ANDA Product (when the dose counter is in the inhaler housing) is very similar to the location of the aperture 74 in the inner wall of the inhaler housing that is depicted in Figure 7B of the '289 Patent below. *See, e.g.*, CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

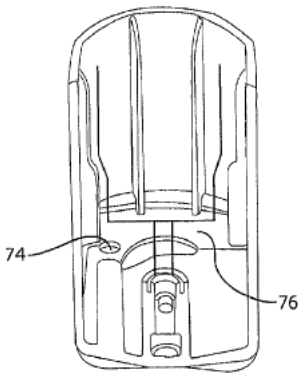


FIG. 7B

As is visible from Figure 7B, Aperture 74 is located in a surface that is part of the inhaler's inner wall, but perpendicular to the direction of the canister's movement during actuation. The remainder of the dose counter's mechanism lies underneath that surface, and the actuation member (not shown in Figure 7B) extends upwardly through the aperture in the surface. As is evident from the images Mr. Anderson provides of Cipla's ANDA Product in Paragraph 103 of his Rebuttal Report, the lid of the dose counter is situated in precisely the same manner when the dose counter is placed inside the inhaler.

See also CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings). Thus, the only difference between the claimed feature and the one present in Cipla's

ANDA Product is that the aperture—despite being located in a very similar location and orientation within the inhaler body and relative to the rest of the dose counter—is formed within the dose counter's lid, rather than a portion of the inhaler's inner wall. Said differently, the only difference between the claimed feature and the equivalent one in Cipla's ANDA Product is that the dose counter lid is not physically molded from the same piece of plastic as the rest of the inner wall of the inhaler body, despite being located in a substantially identical place within the inhaler body as the portion of the inner wall containing the aperture that is shown, for example, in Figure 7B of the '289 Patent. That difference is insubstantial, and in both the claimed feature and Cipla's ANDA Product, the recited actuation member extends from an area below the aperture, where the main body of the dose counter is located, upwardly through the aperture and into the canister housing.

82. **Function-Way-Result Test.** Cipla's ANDA Product also satisfies this limitation under the doctrine of equivalents, as I explain in my Opening Report. Lewis Opening Rep. ¶¶ 137-39. In particular, the claimed feature and the feature present in Cipla's ANDA Product both "perform the function of allowing the actuation member to transmit motion from the medicament canister to the actuator, by way of creating an opening, open space, or hole in the inner wall through which the actuation member can extend, to obtain the result of allowing the dose counter to actuate." Lewis Opening Rep. ¶ 137. Mr. Anderson disagrees, stating that the aperture in the lid of the dose counter of Cipla's ANDA Product does not perform the function of "creating an opening, open space, or hole in the inner wall through which the actuation member can extend" in the same way that the aperture recited in Asserted Claim 3 does. Anderson Rebuttal Rept. ¶ 109. Again, Mr. Anderson's only complaint appears to be that the piece of plastic in which the aperture is located in Cipla's ANDA Product is not physically connected to

the piece of plastic that forms the inner wall of the canister housing. In my opinion, the presence or absence of this physical connection is immaterial and does not alter the function, way, or result associated with the aperture it contains. In other words, the hole in the lid of the dose counter performs its function in the same way as the hole shown in Figure 7B of the '289 Patent, a feature Mr. Anderson appears to interpret as coextensive with the meaning of this limitation.

d. Claim 5

83. Asserted Claim 5 depends from Asserted Claim 4 and recites "the inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." Cipla's ANDA Product infringes Asserted Claim 5. Opening Rep. ¶¶ 144-49.

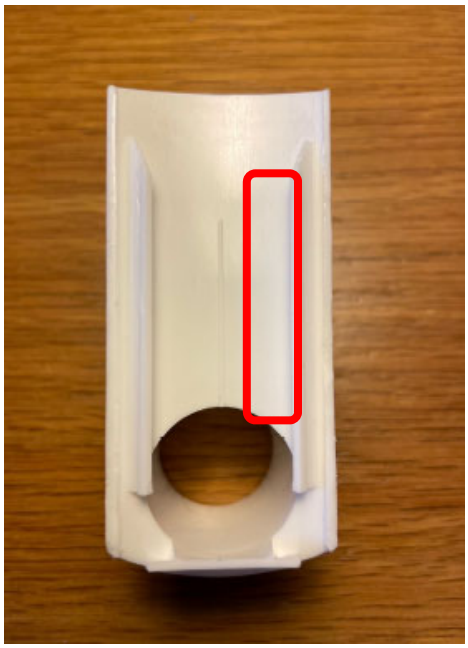
84. I have been informed that the parties have proposed different constructions for the term "step[(s)] formed thereon." I have set forth those competing constructions below:

Term	**Teva's Construction**	**Defendants' Construction**
"step[(s)] formed theereon"	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a location of changing width dimension thereon."	"A stepwise increase in the extent to which the support rail extends inwardly."

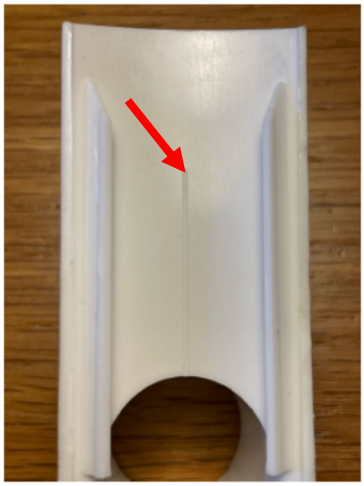
85. I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under either proposed construction.

86. Mr. Anderson points to paragraph 146 of my Opening Report, and alleges that the image it contains shows only a single arrow identifying the only step present on any inner wall canister support formation in Cipla's ANDA Product. Mr. Anderson is incorrect, as that is not what my Opening Report states or reflects. To the contrary, in paragraph 146-147, I make clear

that each of the ribs in Cipla's ANDA Product has a step located in an analogous position—i.e., the top, "end" of the rail. The image I utilized from Cipla's files to demonstrate this simply does not depict the rail on which Mr. Anderson's analysis is focused. Indeed, I state that "Cipla's mounting tab**s** and rib**s** vary in width (i.e., the extent to which **they** extend horizontally into the canister housing) at certain points along **their** length." Lewis Opening Rep. ¶ 146 (emphasis added). [redacted] I further explain that (1) "Cipla's ANDA Product comprises support rail**s** (i.e., what Cipla refers to as "rib**s**" or "mounting tab**s**"); (2) Cipla's support rail**s** **have** **step-wise increases** in the extent to which **they** extend inwardly into the canister housing; and (3) the shape of Cipla's support rail**s** facilitates step-wise insertion of the medicament canister into the canister housing." Lewis Opening Rep. ¶ 148 (emphasis added). *See also* Lewis Opening Rep. ¶ 165-166 (making clear that my doctrine of equivalents theories apply to each and every support rail). Regardless, it is my opinion that the support rail circled below contains "a step formed thereon."



87. Mr. Anderson also suggests that the support rail closest to the inhaler mouthpiece "does not have any structure that could possibly be construed as a step (under either construction)." Anderson Rep. ¶ 116. I disagree. The fact that this rib is smaller than other ribs does not mean it lacks an end that forms a step—such an end is plainly visible in the image Mr. Anderson provides, and I have identified it here with a red arrow, although no such annotation is necessary. Mr. Anderson does not argue that this support rail lacks an end, nor does he suggest that whether or not such an end is a step depends on which of the parties' constructions the Court adopts. Nor does Mr. Anderson dispute that this structure is equivalent to a step under either parties' construction.



88. Accordingly, as my Opening Report makes clear, each of the ribs in Cipla's ANDA Product—including the one identified with the red arrow in the image above) contains a "step formed thereon" or a structure that is insubstantially different from the recited step. Indeed, the structure of Cipla's support rails facilitate easy insertion of the medicament canister into the housing by providing broader and narrower sections, to facilitate step-wise insertion of the medicament canister into the canister housing without interfering with other components. *See, e.g.*, Cipla Samples. The shape of Cipla's support rails also perform substantially the same function in substantially the same way to obtain the same result as the claimed steps, in that both facilitate easy insertion of the medicament canister into the canister housing, by way of providing broader and narrower sections, to obtain the result of facilitating step-wise insertion of the medicament canister into the canister housing without interfering with other components. *See, e.g.,* Cipla Samples. Cipla's ANDA Product thus infringes Asserted Claim 3.

e. Claim 8

89. Asserted Claim 8 depends from Asserted Claim 4 and recites "the inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." As I explained in my

Opening Report, Cipla's ANDA Product infringes Claim 8. Lewis Opening Rep. ¶¶ 166-75.

90. I have been informed that the parties have proposed different constructions for the term "step[(s)] formed thereon." I have set forth those competing constructions below:

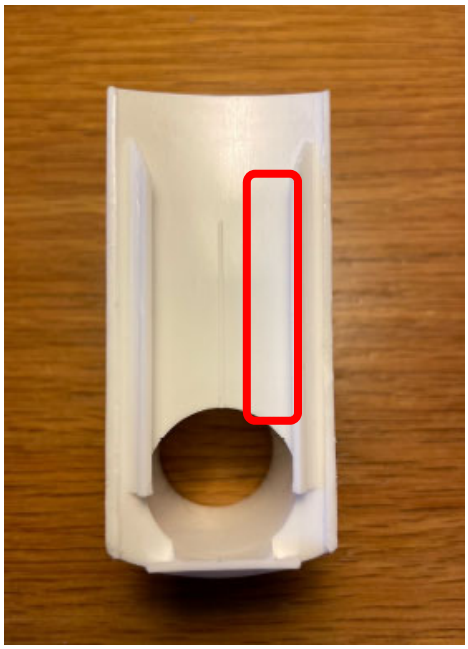
Term	**Teva's Construction**	**Defendants' Construction**
"step[(s)] formed thereon"	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a location of changing width dimension thereon."	"A stepwise increase in the extent to which the support rail extends inwardly."

91. I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla's ANDA Product infringes under either proposed construction.

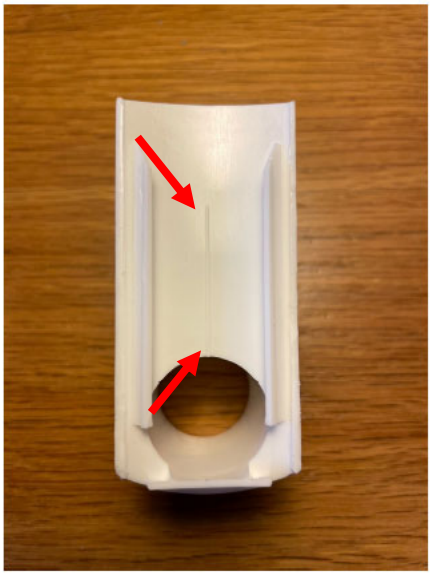
92. Mr. Anderson points to paragraph 167 of my Opening Report, and alleges that the image it contains shows only a single arrow identifying the only inner wall canister support formation in Cipla's ANDA Product that has two steps formed thereon. Anderson Rebuttal Rep. ¶¶ 119-20. Mr. Anderson is incorrect, as that is not what my Opening Report states or reflects. To the contrary, in paragraphs 166-168, I make clear that several of the ribs in Cipla's ANDA Product has two steps formed thereon located in analogous positions to those shown in the image in paragraph 167—i.e., the top, "end" of the rail and the bottom "end" of the rail. The image I utilized to demonstrate this simply does not depict the rail on which Mr. Anderson's analysis is focused. [redacted]

[redacted]

[redacted] Regardless, it is my opinion that the support rail circled below contains "two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body."



93. Mr. Anderson also claims it is not clear what structure I assert is the second of the "two steps" Asserted Claim 8 requires. Anderson Rebuttal Rep. ¶ 121. Mr. Anderson's subsequent opinions belie this fact—I identified the bottom of the ribs in Cipla's ANDA Product, which "end"—just as Mr. Anderson notes. Again, I do not believe the image of Cipla's ANDA product provided by Mr. Anderson requires any annotation, but for clarity, the support rail on which he focuses his opinion has "two steps" located at the top and bottom ends of the rail, at which I have placed red arrows below.



94. Mr. Anderson does not appear to be confused by my opinion or unaware of where I believed the steps on this rail to be located—rather, he seems to disagree that the end of a support rail can be a step under either party's construction. Anderson Rebuttal Rep. ¶ 121. That is simply false. I have reviewed the portion of the transcript of the claim construction hearing during which Teva explained its construction of this term to the Court. Claim Construction Tr. at 78-79. There, Teva's counsel stated explicitly that that the top and bottom ends of a support rail were steps under Teva's construction:

> The most concrete I know how to make this is to say that Teva's position is that the end of the support rail can be a step. That could be at the top of the support rail. . . . It could be at the bottom of the support rail. If the bottom of the support rail doesn't, sort of, dead end as it does in this particular embodiment into a piece of wall in the inhaler. So if there is, you know, if the rail just stops in midair and then the body of the inhaler keeps going, that could also be a step.

Claim Construction Tr. at 78-79. *See also* Claim Construction Tr. at 81 ("I don't know where our disagreement is here except to say that we think inclines and ends of rails can be steps."), 82 ("If it changes width, that's where we would call it a step. And that change could happen sort of at the dead end of the rail at the top or the bottom."). I also reviewed the Defendants' discussion

of this term in the transcript, and I do not understand them to have disagreed that the end of a support rail could be a step. Claim Construction Tr. at 80-81. Mr. Anderson's opinion that the ends of support rails are not steps thus appears inconsistent with both parties' constructions.

95. **Insubstantial Differences Test.** As I explained in my opening report, in the event the support rail I have identified in Cipla's ANDA Product does not literally infringe Claim 8 of the '289 Patent, Cipla's ANDA Product infringes under the doctrine of equivalents. The features at the top and bottom of the support rail identified above are insubstantially different than the recited "steps formed thereon." Lewis Opening Rep. ¶¶ 170-73. As I have explained, the support rail in question does not extend all the way to the top of the inhaler body—it's top "end" thus helps facilitate insertion of the canister into the inhaler body without interfering with other inhaler components, just as the claimed steps are intended to do. The second feature I have identified in Cipla's ANDA Product as equivalent to a step at the bottom end of the rail is designed to avoid interfering with orifice through which the medicament fires. Lewis Opening Rep. ¶ 174. I disagree with Mr. Anderson that avoiding interference with other inhaler components is a function "entirely divorced" from my "assertions regarding insertion of the canister." Anderson Rebuttal Rep. ¶ 124. To the contrary, a feature that assisted in step-wise insertion of the canister would not be useful feature if it also interfered with other dose counter components—these purposes are thus closely tied together.

96. **Function-Way-Result Test.** Mr. Anderson also takes issue with my opinion that, in the event the features I have identified in Cipla's ANDA Product do not literally satisfy claim 8, they do so under the doctrine of equivalents because they perform substantially the same function in substantially the same way to obtain the same result. Lewis Opening Rep. ¶¶ 173-75. Mr. Anderson again takes issue with my connection of the bottom end of the identified support

rail as avoiding interference with other inhaler components, because he suggests that is not related to insertion of the canister. Anderson Rebuttal Rep. ¶¶ 125-26. Again, I disagree—the function of the rails is to facilitate canister insertion, but the result is that they must do so without interfering with other components. Both steps contribute to the performance of this function while achieving all features of the result—by ending before the bottom of the inhaler, the rail avoids interfering with other inhaler components such as the orifice.

2. Cipla's ANDA Product Infringes the '587 Patent

a. Claim 1

97. Asserted Claim 1 of the '587 Patent and Asserted Claim 1 of the '289 Patent are identical, except for the following **underlined** language:

'289 Patent, Claim 1	**'587 Patent, Claim 1**
1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, **the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.**	1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, **wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first**

	inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.

Whereas Asserted Claim 1 of the '289 Patent requires the inner wall canister support formation, the actuation member, and the central outlet port to lie in a common plane coincident with the longitudinal axis X, Asserted Claim 1 of the '587 Patent additionally requires those components to lie in a common plane coincident with the longitudinal axis X, "such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler."

98. I have been informed that the parties have agreed that the term "protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler" should be constructed to mean "guards against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter's actuator enough to cause unwanted incrementing (or decrementing) of the dose counter". I have applied that construction in performing my analysis.

99. As I stated in my Opening Report, Cipla's ANDA Product infringes Asserted Claim 1 of the '587 Patent. Lewis Opening Rep. ¶¶ 176-85. Mr. Anderson's opinion to the contrary is flawed. In particular, Mr. Anderson's disagreement is premised on his incorrect assertion that the rib closest to the inhaler mouthpiece "does not protect against unwanted actuation of the dose counter" and "has no impact on actuation of the dose counter because rocking the canister in the direction of that rib cannot create unwanted actuation regardless of whether the rib is present." As I have demonstrated in direct response to Mr. Anderson's

inaccurate statement, rocking of the canister sufficient to record an unwanted count *can* occur when this rib is removed. *See* TEVADOC-00000843 (Cipla); *s* [redacted] *see also supra* Section V.A.2.

100. Additionally, the testing I reported in Paragraph 181 of my Opening Report confirms the important role the inner wall canister support formations in Cipla's ANDA Product play in reducing canister rocking. Mr. Anderson criticizes that testing because, he suggests, it was improper for me to remove all of the support ribs in the inhaler, and instead I should have removed only the rib closest to the inhaler mouthpiece in order to conduct a valid test. I disagree. I tested the rocking of the canister specifically in the "front to back" direction, which is the direction affected by the absence of the support rib closest to the mouthpiece.

101. In particular, Mr. Anderson states that the two largest ribs in Cipla's ANDA Product, the "mounting tabs" do not lie in a common plane with any actuation member and the central outlet port, but that "given their size relative to the other ribs, removing the mounting tabs could potentially increase the amount of movement of the canister within the housing." Anderson Rebuttal Rep. ¶ 134. I disagree that removal of the mounting tabs would have been improper, but to be clear, I did not remove the mounting tabs during my testing. However, I note that I did *not* in fact remove the mounting tabs in performing this experiment. An image depicting the 80 mg Cipla ANDA Product Sample after I had altered it to perform the experiment I reported in paragraph 181 of my Opening Report is shown below:

102. I also disagree that my measurement of "side-to-side" movement is irrelevant because it does not measure rocking in the direction of the actuation member that is the of Mr. Anderson's analysis. Asserted Claim 1 of the '587 patent does not require reduction in rocking in the direction of the actuation member, but rather reduction in rocking relative to the main body of the inhaler. "Side-to-side" rocking is rocking relative to the main body of the inhaler, and reducing such rocking can prevent unwanted actuation of the dose counter in Cipla's ANDA Product—not least because Cipla's ANDA Product contains multiple actuation members, and also because the greater the freedom of movement of the canister generally, the greater possibility of rebound movement in the direction of a given actuation member.

103. Mr. Anderson also reasserts, incorrectly that none of the ribs in Cipla's ANDA Product "could perform" the function of "protect[ing] against unwanted actuation of the dose counter." Anderson Rebuttal Rep. ¶ 136. Mr. Anderson is incorrect for several reasons. First, I do not agree with Mr. Anderson's interpretation of Asserted Claim 1 or the agreed upon construction of its final limitation—I see nothing in that claim or the agreed upon construction

that requires that, but for the claimed inner wall canister support formation, the inhaler would or could have experienced rocking that would or could have caused a count. The claimed inner wall canister support formation must simply *protect against* the occurrence of such rocking, even if it does not protect against all, minor rocking. (In other words, the claimed inner wall canister support formation need not completely eliminate canister rocking.)

104. Regardless, even were I to adopt, arguendo, Mr. Anderson's flawed understanding of Asserted Claim 1, I have demonstrated that in the absence of the inner wall canister support formation Mr. Anderson analyzes (i.e., the one in the center of the inner wall closest to the patient when in use), it is indeed possible to rock the canister sufficiently to cause Cipla's ANDA Product to record an unwanted count, reflecting reduced dose counter accuracy. *See* TEVADOC-00000843 (Cipla); [redacted] *see also supra* Section V.A.2.

b. Claim 12

105. Asserted Claims 1 and 12 of the '587 Patent are identical, except for the following **underlined** language:

'587 Patent, Claim 1	**'587 Patent, Claim 12**
1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,	12. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, **wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.**	wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, **the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against dose counter errors by reducing rocking of the medicament canister towards or away from the actuation member.**

Whereas Asserted Claim 1 of the '587 Patent requires the inner wall canister support formation, the actuation member, and the central outlet port to lie in a common plane coincident with the longitudinal axis X, "such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler," Asserted Claim 12 requires those components to lie in a common plane "such that the first inner wall canister support formation protects against dose counter errors by reducing rocking of the medicament canister towards or away from the actuation member."

106. As I explained in my Opening Report, Cipla's ANDA Product infringes Asserted Claim 12 of the '587 Patent. Lewis Opening Rep. ¶¶ 190-94. At least the inner wall canister support formation at the front of the inhaler "protects against unwanted dose counter errors by reducing rocking of the medicament canister towards or away from the actuation member," just as Asserted Claim 12 requires. The data I provided in Paragraph 181 of my Opening Report establishes that this inner wall canister support formation reduces front-to-back canister rocking

in Cipla's ANDA Product.

107. Mr. Anderson also reasserts, incorrectly, that none of the ribs in Cipla's ANDA Product perform the function of "protect[ing] against unwanted actuation of the dose counter." Anderson Rebuttal Rep. ¶ 145. Mr. Anderson is incorrect for several reasons. First, I do not agree with Mr. Anderson's interpretation of Asserted Claim 12 or the agreed upon construction of its final limitation—I see nothing in that claim or construction that requires that, but for the claimed inner wall canister support formation, the inhaler would or could have experienced rocking that would or could have caused a count. The claimed inner wall canister support formation must simply *protect against* such rocking, even if it does not protect against all, minor rocking. (In other words, the claimed inner wall canister support formation need not completely eliminate canister rocking.)

108. Regardless, even were I to adopt, arguendo, Mr. Anderson's flawed understanding of Asserted Claim 12, I have demonstrated above that, in the absence of the inner wall canister support formation closest to the canister mouthpiece, it is possible to rock the canister sufficiently to cause an unwanted count and thereby reduce dose counter accuracy. *See* TEVADOC-00000843 (Cipla); [redacted] *supra* Section V.A.2.

109. Mr. Anderson also takes issue with my statement that "[w]hen the medicament canister rocks away from the actuation member, the medicament canister comes into contact with a lower portion of the inner wall canister support formation." Lewis Opening Rep. ¶ 191; *contra* Anderson Rebuttal Rep. ¶¶ 143-44. Mr. Anderson again conflates theory as applied to two dimensional drawings with the real-world problems faced in three-dimensional inhaler design. Mr. Anderson's images in Paragraph 142 of his Rebuttal Report assume that the only way in

which the canister can rock is by pivoting at the point where the valve stem enters the canister while the canister is otherwise at rest. This is not true. As I demonstrated, the canister can rock before or after it is depressed—indeed, in some instances such rocking (in the absence of support rails) can cause the device to count a dose without expelling medication. *See* TEVADOC-00000843 (Cipla); [redacted] *supra* Section V.A.2. In other circumstances, the valve stem can bend, meaning that canister rocking is not limited to the angles Mr. Anderson has identified. Regardless, Asserted Claim 12 requires "reducing rocking of the medicament canister towards **or** away from the actuation member" not "towards **and** away from the actuation member"—my statement that when the medicament canister rocks away from the actuation member, it comes into contact with a lower portion of the inner wall canister support formation" is thus accurate but unnecessary to evaluate infringement of Asserted Claim 12.

c. Claim 13

110. Asserted Claim 13 recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister retained in the canister housing and movable relative hereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and
> wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

'587 Patent, claim 13.

111. As I explained in my Opening Report, Cipla's ANDA Product infringes Asserted Claim 13 of the '587 Patent. Lewis Opening Rep. ¶¶ 195-98. Mr. Anderson disagrees with my

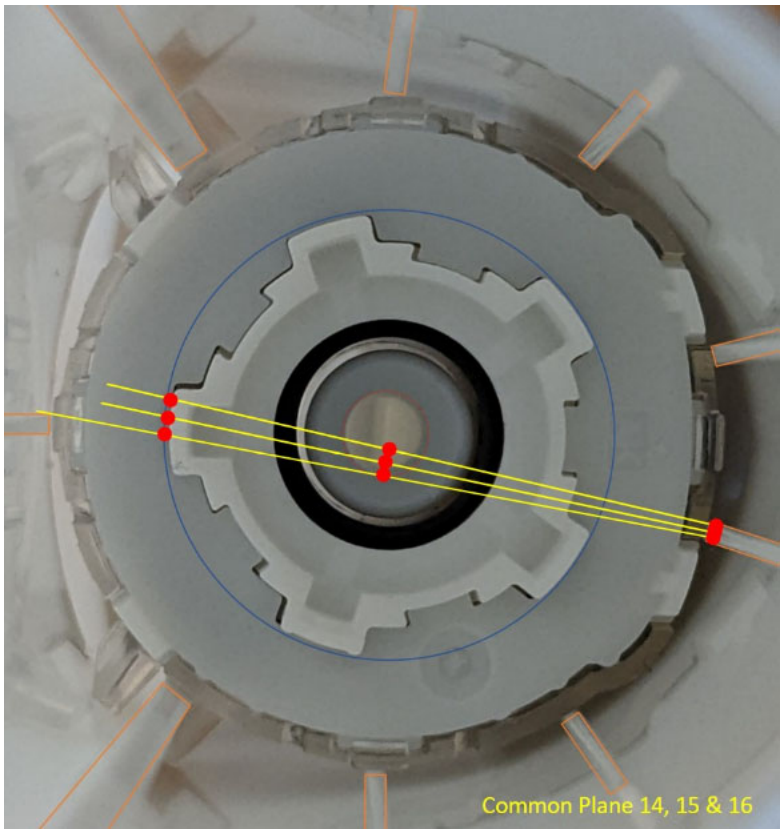
opinions for the same reasons as he offers for Asserted Claims 1 and 3 of the '289 Patent. Anderson Rebuttal Rep. ¶¶ 147-50. I therefore disagree with Mr. Anderson for all the reasons I explained above, in the context of Asserted Claims 1 and 3 of the '289 Patent. Accordingly, I incorporate by reference my analysis of Asserted Claims 1 and 3 of the '289 Patent as though fully set forth herein, *supra* Sections V.A.1.a and V.A.1.c, and I do not repeat those analyses here solely for the sake of brevity.

d. Dependent Claims

1) Claim 11

112. Asserted Claim 11 depends from Asserted Claim 1 and recites "the inhaler as claimed in claim 1, further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X." As I explained in my Opening Report, Cipla's ANDA Product Infringes Asserted Claim 11. Lewis Opening Rep. ¶¶ 186-89.

113. Mr. Anderson suggests I offer no analysis of this limitation. That is incorrect. I incorporated my analysis of Asserted Claim 1, which indicates that it is possible to draw multiple common planes through inner wall canister support formations and actuation members of Cipla's ANDA Product, and that several of those planes pass through an actuation member. Further, some of those planes pass through an additional inner wall canister support formation. No drawing is necessary to illustrate this fact, but I have provided such an illustration below.



(Cipla 80mg ANDA Product Sample)

2) Claim 16

114. Asserted Claim 16 depends from Asserted Claim 15 and recites "the inhaler as claimed in claim 15, wherein the support rail includes a step formed thereon."

115. As I explained in my Opening Report, Cipla's ANDA Product infringes Asserted Claim 16. Lewis Opening Rep. ¶¶ 199-202. Mr. Anderson disagrees with my infringement opinion as to Asserted Claim 16 of the '587 Patent for all the same reasons as he asserts with respect to Asserted Claim 5 of the '289 Patent. Anderson Rebuttal Rep. ¶ 156. As I explained in my Opening Report, ¶¶ 144-49, and above, *supra* Section V.A.1.d, Cipla's ANDA Product infringes Asserted Claim 5 of the '289 Patent. I therefore disagree with Mr. Anderson for all the reasons I explained above, in the context of Asserted Claim 5 of the '289 Patent. Accordingly, I incorporate by reference my analysis of Asserted Claim 5 of the '289 Patent above, *supra*

Section V.A.1.d, as though fully set forth herein, and I do not repeat it here solely for the sake of brevity.

3) Claim 19

116. Asserted Claim 19 depends from Asserted Claim 15 and recites "the inhaler as claimed in claim 15, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along the inside surface of the main body."

117. As I explained in my Opening Report, Cipla's ANDA Product infringes Asserted Claim 19. Lewis Opening Rep. ¶¶ 199-202. Mr. Anderson disagrees with my infringement opinion as to Asserted Claim 16 of the '587 Patent for all the same reasons as he asserts with respect to Asserted Claim 8 of the '289 Patent. Anderson Rebuttal Rep. ¶ 157. As I explained in my Opening Report, ¶¶ 166-75, and above, *supra* Section V.A.1.e, Cipla's ANDA Product infringes Asserted Claim 8 of the '289 Patent. I therefore disagree with Mr. Anderson for all the reasons I explained above, in the context of Asserted Claim 8 of the '289 Patent. Accordingly, I incorporate by reference my analysis of Asserted Claim 8 of the '289 Patent above, as though fully set forth herein, and I do not repeat it here solely for the sake of brevity.

4) Claim 20

118. Asserted Claim 20 depends from Asserted Claim 15 and recites "the inhaler as claimed in Asserted Claim 15, wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture."

119. As I explained in my Opening Report, Cipla's ANDA Product infringes Asserted Claim 20. Lewis Opening Rep. ¶¶ 203-08. Mr. Anderson asserts that Cipla's ANDA Product does not infringe Asserted Claim 20 because Cipla's ANDA Product lacks the recited aperture. Anderson Rebuttal Rep. ¶ 160. As I explained above in the context of Asserted Claim 3 in the '289 Patent, *supra* Section V.A.1.c, Mr. Anderson is incorrect. I therefore disagree with Mr.

Anderson for all the reasons set forth in the context of Asserted Claim 3 of the '289 Patent. Accordingly, I incorporate by reference my analysis of Asserted Claim 8 of the '289 Patent above, *supra* Section V.A.1.c, as though fully set forth herein, and I do not repeat it here solely for the sake of brevity.

120. In addition, Mr. Anderson asserted that Cipla's ANDA Product does not infringe Asserted Claim 20 because "the ribs in Cipla's ANDA Product are each a constant width" and thus "even if there were an aperture . . . Cipla's ANDA Product does not infringe Claim 20 either literally or under DOE." Anderson Rebuttal Rep. ¶ 161. Mr. Anderson is incorrect. The support rail at the front of the inhaler, for example, is not a constant width along its length. To the contrary, at the top of the inhaler, the support rail has a width of zero, and then that width increases and remains constant until the rail approaches the mouthpiece, as is visible in Mr. Anderson's images of Cipla's ANDA Products (for example, in Anderson Rebuttal Report paragraph 116):

This is also apparent from physical inspection of Cipla's ANDA Product samples. *See, e.g.*, Cipla Samples. The aperture of Cipla's ANDA Product occurs above the bottom end of the front

rail—indeed, Mr. Anderson explains that "the medicament canister in Cipla's ANDA Product is blocked from the bottom of the ribs by the dose counter itself." Anderson Rebuttal Report 124. Thus, where the front rib of Cipla's ANDA Product comes closest to the aperture, it is also at its greatest width dimension. *See, e.g.,* Cipla Samples.

3. Teva's Equivalents Theories Do Not Ensnare the Prior Art

121. In his Rebuttal Report, Mr. Anderson refers back to the opinions in his Opening Report and states that "to the extent that Dr. Lewis contends that the Cipla ANDA Product meets any claim of the '289 Patent or '587 Patent under the doctrine of equivalents, such expansion of the claims improperly ensnares the prior art, specifically WO 2007/124406 ('the '406 Publication')." Anderson Rebuttal Rep. ¶ 162 (citing Anderson Opening Rep. § XIII). Mr. Anderson further states: "as explained in Section XV of my Opening Report, to the extent the claims of the '289 Patent and '587 Patents are expanded under the doctrine of equivalents to include the Cipla ANDA Product, each limitation of '289 Patent and '587 Patent also reads on at least the third embodiment of the '406 Publication." Anderson Rebuttal Rep. ¶ 163 (citing Anderson Opening Rep. § XV). I disagree with Mr. Anderson.

122. As I explained in my Rebuttal Report and below in further detail, Mr. Anderson fails to demonstrate that Cipla's ANDA Product "practices the invention" of the '406 Publication, including what Mr. Anderson refers to as the "third embodiment." I have reviewed the documents that Mr. Anderson cites as the basis for that assertion (*see* Anderson Opening Rep. § XIII), and I disagree with his comparison between the '406 Publication and Cipla's ANDA Product. As I explain in my Rebuttal Report, the '406 Publication consists of a series of two-dimensional images and text. Those disclosures do not support comparisons with the level of accuracy that Mr. Anderson purports to have conducted his analysis. That is especially true with respect to the '289 and '587 Patents, which require an evaluation of the relative positions of

certain components (including, for example, the "inner wall canister support formation," "actuation member," and "central outlet port"). *See* Lewis Rebuttal Rep. §§ IV.A, VI.A.1.a, VI.A.2.a.

123. Nevertheless, even from the images in the '406 Publication, which I explain in my Rebuttal Report, it is apparent that Cipla's ANDA Product contains additional features recited by the Asserted Claims that the '406 Publication does not disclose. Among other deficiencies, the '406 Publication nowhere discloses an inhaler body with the above-mentioned inner wall canister support formation. It therefore cannot disclose the arrangement of an inner wall canister support formation, actuation member and central outlet port in a common plane. Thus, as I opined in my Rebuttal Report, Mr. Anderson fails to demonstrate that the '406 Publication (including what Mr. Anderson refers to as the "third embodiment") anticipates or render obvious the Asserted Claims of the '289 or '587 Patents. Certain components disclosed in the '406 Publication and Cipla's ANDA Product also appear to have obvious differences in their size, shape, and orientation, including with respect to the shape of what Cipla refers to as an "indexer" and the orientation of what Cipla refers to as a "leaf spring." *Compare, e.g.*, '406 Publication, Figs. 21, 26 *with* Cipla Samples; CIPLA-BDI_0156579 (Design Drawing). These differences, combined with the lack of information the '406 Publication, would compel the POSA to conclude that Cipla's ANDA Product did not "practice the invention" of the '406 Publication. I therefore disagree with Mr. Anderson and incorporate my prior analysis as though fully set forth herein. *See* Lewis Rebuttal Rep. §§ IV.A, VI.A.1.a, VI.A.2.a.

B. Cipla's ANDA Product Infringes the '156 Patent

1. Mr. Anderson's "Summary of the Relevant Prosecution History"

124. Like Mr. Anderson's Supplemental Report, Mr. Anderson's Rebuttal Report sets forth a lengthy summary of selected portions of the '156 Patent's prosecution history. *Compare*

Anderson Supp. Rep. § XII.A *with* Anderson Rebuttal Rep. § XIII.A. As in my Rebuttal Report, I have reviewed the portions of the prosecution history that Mr. Anderson mentions. *See* '156 Patent Prosecution History, Original Application (Apr. 29, 2015); Office Action (June 17, 2016); Office Action Response (Sep. 9, 2016); Office Action (Oct. 20, 2016); Office Action Response (Feb. 21, 2017); Office Action (Mar. 13, 2017); Office Action Response (Apr. 20, 2017); Office Action (May 5, 2017); Office Action Response (Aug. 22, 2017); Office Action (Sept. 13, 2017); Office Action Response (Mar. 13, 2018); Notice of Allowance (May 31, 2018); U.S. Patent No. 6,446,627 ("Bowman").

125. In my opinion, the prosecution history of the '156 Patent does not support Mr. Anderson's opinions that Cipla's ANDA Product fails to satisfy the requirements of the Asserted Claims of the '156 Patent, and in fact, contradicts them. For example, as I explain below in further detail, the prosecution history contradicts Mr. Anderson's opinion that Cipla's ANDA Product does not infringe the limitation in Asserted Claim 1 that requires an "actuator pawl" to be "below a datum plane which passing through a shoulder of the valve stem block." *See, e.g.*, *infra* Section V.B.2.g. Thus, in my opinion, Mr. Anderson's reliance on that prosecution history is misplaced. I incorporate that analysis as though fully set forth herein.

2. Claim 1

126. Asserted Claim 1 of the '156 Patent recites as follows:

> 1. A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:
> a ratchet wheel having a plurality of circumferentially spaced teeth,
> an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in
> response to canister motion to drive the ratchet wheel to

rotate,
a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate,
the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth, and
a dosage indicator associated with the count pawl,
wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth,
wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration,
the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count,
wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

Asserted Claims 9 and 11-13 depend, directly or indirectly, from Asserted Claim 1.

127. As stated in my Opening Report, I have been informed that the parties have agreed upon constructions for the terms "body," "associated with," "actuator," "actuator pawl arranged to engage with a first tooth of the ratchet wheel," "wall surfaces separating the canister receiving portion and the counter chamber," and "ratchet wheel." *See supra* Section II.B. I have applied those constructions in performing my analysis.

128. As further stated in my Opining Report, I have been informed that the parties have proposed different constructions for the terms "canister fire sequence," "first reset position," "canister fire configuration," "count configuration," "datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister," and "count pawl."

No.	Claim Term	Teva's Construction	Defendants' Construction
5	"first reset position" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the canister fire configuration"	"configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel"
6	"canister fire sequence" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament"	"process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the start configuration to the reset configuration, to the [fire configuration as, to the count configuration, before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel."
7	"canister fire configuration" '156 Patent, claims 1, 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a configuration of the dose counter in which the medicament canister fires medicament"	"configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected"

No.	Claim Term	Teva's Construction	Defendants' Construction
8	"count configuration" '156 Patent, claims 1, 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a configuration of the dose counter whereby the dosage indicator has indicated a count"	"configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose counter has counted one dose"
9	"datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister"	"plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet"
16	"count pawl" '156 Patent, claims 1, 9	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the rachet wheel"	"a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel"

129. I have not been asked to provide an opinion as to which proposed constructions are correct, and I express no opinion on that issue. As I explain in my Opening Report, in my opinion, Cipla's ANDA Product satisfies the limitations of this claim, both literally and under the doctrine of equivalents, under both sides' proposed constructions. I incorporate that analysis as though set forth fully herein. *See* Lewis Opening Rep. § VII.C.4.

130. In his Rebuttal Report, Mr. Anderson opines that Cipla's ANDA Product does not satisfy the requirements of this claim, literally or under the doctrine of equivalents, under either side's proposed construction based on his analysis of what he refers to as "Limitations 1A-1F." Anderson Rebuttal Rep. § XII.B.(i). As I explain below in greater detail, I disagree with Mr. Anderson on each of these issues.

a. Cipla's ANDA Product Comprises "A Ratchet Wheel Having a Plurality of Circumferentially Spaced Teeth" (Limitation 1A)

131. As I explain in my Opening Report, Cipla's ANDA Product satisfies this limitation literally, under both sides' proposed constructions, because it comprises (what Cipla refers to as) a "units teeth ring." I incorporate that analysis as through set forth fully herein. *See* Lewis Opening Rep. § VIII.C.1.d.1).

132. In his Rebuttal Report, Mr. Anderson opines that Cipla's ANDA Product does not satisfy this limitation literally or under the doctrine of equivalents under either sides' proposed constructions. *See* Anderson Rebuttal Rep. § XII.B.(i).a). As I explain below in greater detail, I disagree with Mr. Anderson on each of these issues.

1) Literal Infringement

133. In his Rebuttal Report, Mr. Anderson opines that Cipla's ANDA Product does not satisfy this limitation literally because Cipla's "units teeth ring" is not a "ratchet wheel having a plurality of circumferentially spaced teeth." *See* Anderson Rebuttal Rep. § XII.B.(i).a).1). In rendering this opinion, Mr. Anderson does not appear to differentiate between Teva's and Defendants' proposed constructions. Regardless, as I explain below, Mr. Anderson is incorrect in opining that Cipla's units teeth ring is not a "ratchet wheel having a plurality of circumferentially spaced teeth." Thus, in my opinion, Cipla's ANDA Product satisfies the requirements of this limitation under either side's proposed construction.

134. Mr. Anderson identifies two purported differences between Cipla's "units teeth ring" and the claimed "ratchet wheel." First, Mr. Anderson states that Cipla's "units teeth ring" is a "ring" not a "wheel." According to Mr. Anderson, a "wheel" is a "structure which rotates on its own," whereas a "ring" "lacks any central structure on which it rotates." Anderson Rebuttal Rep. ¶ 184. To illustrate that purported distinction, Mr. Anderson refers to a "bike wheel," which "can spin or rotate on its own around an axis." Anderson Rebuttal Rep. ¶ 184. Mr. Anderson contrasts this with Cipla's "units teeth ring," which in his view, "is a hollow ring, that is locked into the units display ring by 4 external protrusions." Anderson Rebuttal Rep. ¶ 184. Second, Mr. Anderson states that the teeth in Cipla's "units teeth ring" are "not arranged to engage with a pawl," and that Cipla's ANDA Product lacks any pawl. Anderson Rebuttal Rep. ¶ 185-190. I disagree with each element of Mr. Anderson's analysis.

135. First, Mr. Anderson's purported distinction between "rings" and "wheels" is without basis. Tellingly, Mr. Anderson does not identify any evidence in the '156 Patent or elsewhere that supports his purported distinction, and in my opinion, no such evidence exists. To the contrary, the '156 Patent uses the term "wheel" to describe a variety of rotating structures, without reference to whether they have any central structures. *See, e.g.*, '156 Patent, 3:47-60, 4:34-45, 5:22-6:6, 8:9-12, 10:59-11:2, 12:15-15:34, 17:24-19:66, Figs. 6A-6H, 10A-10F, 15-20. Indeed, many of the structures that the '156 Patent describes as wheels have hollow centers and could be spun around an axis. *See, e.g.*, '156 Patent, Figs. 6A-6H, 10A-10F, 15-20. That usage of the term is consistent with my own and that of others in the inhalation device industry. During my work, I and my colleagues frequently use the terms "ring" and "wheel" interchangeably—including in reference to rotating structures that do not have any central structure around which they rotate.

136. Mr. Anderson's own example of a "bike wheel" illustrates the flaws in his analysis. To take that example, a "bike wheel" can accurately be described as both a "wheel" or a "ring." Although bike wheels rotate around a central axis, as Mr. Anderson states, that does not mean that they are not also "rings." Indeed textbooks commonly do describe "bike wheels" as rings. *See, e.g.*, Levi 2014, at 158 ("Let us now treat the bike wheel as a thin ring of radius *r* with all its mass *m* concentrated in the rim.").[1] In my view, the POSA would similarly view Cipla's "units teeth ring" as a "ratchet wheel."

137. In any event, Mr. Anderson's purported distinction between "wheels" and "rings" fails to demonstrate non-infringement. Assuming for argument's sake, that Mr. Anderson is correct that Cipla's ANDA Product literally comprises a "ring" and not a "wheel," at a minimum, Cipla's "units teeth ring" satisfies the requirements of a "units teeth ring" under the doctrine of equivalents. I address this issue in the Section below and incorporate that analysis as though fully set forth herein.

138. Second, Mr. Anderson's opinions that the teeth in Cipla's "units teeth ring" are "not arranged to engage with a pawl," and that Cipla's ANDA Product lacks any pawl, repeats Cipla's mistaken contentions that the POSA would not understand the triangular protrusions on the bottom of Cipla's "indexer" to be "actuator pawls" or "count pawls." I address these issues at length in my Opening Report and I incorporate that analysis as though set forth fully herein. *See, e.g.*, Lewis Opening Rep. §§ VIII.C.1.d.2)-3).

139. In brief, when a patient presses down on Cipla's medicament canister, the

[1] I appreciate that Levi 2014 is not prior art to the '156 Patent. However, consistent with my experience, the POSA would understand its descriptions of "bike wheels" and "rings"—which both long predate the '156 Patent—to accurately reflect how the POSA would have understood those concepts as of the priority date.

medicament canister pushes down on Cipla's actuator, causing it to move downward. As Cipla's actuator moves downward, a first inner tooth of Cipla's units teeth ring engages with one or more of the triangular protrusions on the bottom of Cipla's actuator, causing the units teeth ring to rotate. As the units teeth ring rotates, a second inner tooth of the units teeth ring engages with one or more of the triangular protrusions on the bottom of Cipla's indexer. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings); Lewis Opening Rep. § VIII.C.1.d.2)-3).

140. Mr. Anderson takes issue with this analysis because, in his view, the POSA would understand the term "actuator pawl" "in the context of the specification to be a structure (typically a bar or lever) adapted to engage with teeth of a ratchet wheel so as to prevent or impart rotational motion to the ratchet wheel" and "specifically be understood to engage with the tooth of the ratchet wheel by pulling the tooth downwards to impart movement." Anderson Rebuttal Rep. ¶ 186. As an initial matter, I do not see any conflict between Mr. Anderson's description of a "pawl" and the operation of the triangular protrusions at the bottom of Cipla's "indexer." In both cases, the structure in question engages with a "ratchet wheel" to "prevent" and "impart" rotational motion. Nevertheless, to the extent that Mr. Anderson suggests that the meaning of "actuator pawl" is narrower because, for example, the POSA would specifically understand it to require a pulling motion, nothing in the '156 Patent or elsewhere supports that proposition. To the contrary, unlike the passages in the '156 Patent's specification that Mr. Anderson relies upon, which specifically use the term "pull,"[2] the claims do not qualify the

[2] *See* '156 Patent, Figs. 6H, 10A-F, 4:34-38, 5:30-34 ("The actuator pawl may be generally U-shaped having to parallel arms arranged to ***pull*** on a central pawl member arranged substantially

manner in which the "actuator pawl" "engages" with the "ratchet wheel." The POSA would therefore understand the claims to encompass any form of engagement, including "pulling" or other forms of engagement, like "pulling."

141. Additionally, Mr. Anderson states that I do not "identify which protrusions allegedly act as 'actuator pawls' and which are acting as 'count pawls.'" Anderson Rebuttal Rep. ¶ 187. As I understand it, Mr. Anderson's concerns are misdirected. I have been informed that an element in the accused product can satisfy multiple claim limitations, as is the case with the protrusions on the bottom of Cipla's "indexer." In this case, one of those protrusions constitutes the "actuator pawl" and another of those protrusions constitutes the "count pawl." Mr. Anderson's assertion that such components "cannot be separated into different parts performing different functions" is therefore without basis. Anderson Rebuttal Rep. ¶ 187.

142. Mr. Anderson also provides a lengthy explanation of the functioning of Cipla's ANDA Product. *See* Anderson Rebuttal Rep. § IX, ¶¶ 188-89. Although Mr. Anderson states that my analysis is "incorrect" based on that explanation, Anderson Rebuttal Rep. ¶ 189, the vast majority of Mr. Anderson's analysis appears to be consistent with my own (although, of course, we use different words in our respective analyses). The source of Mr. Anderson's perceived disagreement with my analysis appears to be the conclusions that he draws from his explanation, rather than the explanation itself—namely, that, according to Mr. Anderson, "the protrusions on the bottom of the bottom of the indexer are neither pulling the teeth of the units teeth ring, nor preventing movement of the units teeth ring, and therefore are not acting as 'pawls.'" Anderson Rebuttal Rep. ¶ 188. In my opinion, those conclusions are both inaccurate and do not follow

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perpendicular thereto. This provides a very reliable actuator pawl which can reliably pull on the teeth of the ratchet wheel."), 13:48-50 ("the actuator pawl 80 ***pulls*** down on one of the teeth 92 of the ratchet wheel 94 and rotates the wheel 94 anticlockwise as shown in Fig. 6D").

from Mr. Anderson's own analysis. Indeed, in explaining the functioning of Cipla's ANDA Product, Mr. Anderson concedes that the protrusions on the bottom of Cipla's ANDA Product come "into contact with the inner ridges of the units teeth ring" and that this "contact slightly shifts the units teeth ring causing the vertical surfaces of the outer teeth of the units teeth ring to misalign with protrusions on the bottom of the lid." Anderson Rebuttal Rep. ¶ 188. Mr. Anderson further concedes that "the protrusions on the bottom of the indexer force the units teeth ring downwards, causing the outer teeth to disengage from the protrusions on the lid." Anderson Rebuttal Rep. ¶ 188. Although Mr. Anderson concludes from this that the protrusions on the bottom of Cipla's "indexer" "are neither pulling the teeth of the units teeth ring, nor preventing movement of the units teeth ring," Anderson Rebuttal Rep. ¶ 188, he ignores that, at a minimum, the contact between the protrusions on the bottom of Cipla's "indexer" and the inner teeth of the "units teeth ring" prevent backward movement of the ring. And his assertion that the protrusions on the bottom of Cipla's "indexer" do not "pull" on the teeth of the "units teeth ring" repeats his mistaken assumption that the "engage[ment]" described in the claim necessarily involves "pulling"—an assumption that lacks any support in or outside of the '156 Patent. *See supra*.

143. In sum, in my opinion, Cipla's ANDA Product satisfies the requirements of this limitation, and Mr. Anderson's contrary opinions do not demonstrate otherwise.

2) Doctrine of Equivalents

144. Mr. Anderson further opines that Cipla's ANDA Product does not satisfy the requirements of this limitation under the doctrine of equivalents. *See* Anderson Rebuttal Rep. § XII.B.(i).a).2). Because Cipla's ANDA Product satisfies the requirements of this claim literally, Cipla's ANDA Product necessarily satisfies the requirements of this claim under the doctrine of equivalents. Nevertheless, I address Mr. Anderson's arguments below for the sake of completeness. I disagree with each of Mr. Anderson's criticisms.

145. **Insubstantial Differences Test.** In my Opening Report, I opined that Cipla's ANDA Product satisfied this limitation under the insubstantial differences test. In his Rebuttal Report, Mr. Anderson criticizes that analysis based on his opinion that Cipla's "units teeth ring is circular, but not 'wheel-like' in that it is missing key aspects of a wheel, including that it does not freely rotate." Anderson Rebuttal Rep. ¶ 192. He further repeats his criticisms of my analysis of the functioning of Cipla's ANDA Product, which I discuss above. Anderson Rebuttal Rep. ¶ 192. I disagree with Mr. Anderson's opinions.

146. Mr. Anderson's statement that Cipla's "units teeth ring" is not "wheel-like" because it is "missing key aspects of a wheel, including that it does not freely rotate" is unsupported. Nothing in the '156 Patent supports Mr. Anderson's assertion that a "wheel" must freely rotate, and in fact, at least some of the examples in the '156 Patent do not appear to rotate freely because they engage with other components of the device, such as, for example, various pawls and anti-backdrive elements. *See, e.g.*, '156 Patent, 3:47-60, 4:34-45, 5:22-6:6, 8:9-12, 10:59-11:2, 12:15-15:34, 17:24-19:66, Figs. 6A-6H, 10A-10F, 15-20. Indeed, even "bike wheels," which Mr. Anderson offers as examples of "wheels" in connection with his opinions on literal infringement (*see, e.g.*, Anderson Rebuttal Rep. ¶ 184) do not rotate freely because they engage with other components of the bicycle, including, for example, breaking mechanisms.

147. Regardless, Mr. Anderson does not offer any reasons why the purported differences that he identifies between Cipla's "units teeth ring" and (what he opines to be) a "wheel" or "wheel-like" element are substantial. As I explain in my Opening Report, both Cipla's "units teeth ring" and the claimed "ratchet wheel" are circular structures that have a plurality of circumferentially spaced teeth, which engage with the components in Cipla's ANDA Product that correspond to the claimed "actuator pawl" and "count pawl." Lewis Opening Rep.

§ VIII.C.1.d.2)-3). Both further transform the linear movement of the component in Cipla's ANDA Product that correspond to the claimed "actuator pawl" to rotational movement. Lewis Opening Rep. § VIII.C.1.d.2)-3). None of the differences that Mr. Anderson identifies anywhere in his report, including the purported differences between "wheels" and "rings," demonstrates otherwise.

148. I address Mr. Anderson's criticisms of my analysis of the functioning of Cipla's ANDA Product in the Section above, and I incorporate that analysis as though fully set forth herein.

149. **Function-Way-Result Test.** In my Opening Report, I also opined that Cipla's ANDA Product satisfied this limitation under the function-way-result test. In his Rebuttal Report, Mr. Anderson states that in identifying the relevant "function," I erred "by looking at [Cipla's ANDA Product] from a 100,000 foot view. At that level, nearly anything is an equivalent." Anderson Rebuttal Rep. ¶ 193. Notwithstanding that, Mr. Anderson proceeds to identify what he characterizes as differences in the ways that Cipla's ANDA Product and the claimed inventions function and their results. *See* Anderson Rebuttal Rep. ¶¶ 194-95. I disagree with each of Mr. Anderson's criticisms.

150. As I explain in my Opening Report in greater detail, both Cipla's "units teeth ring" and the claimed "ratchet wheel" "perform the function of transforming liner movement of the component that corresponds to the actuator pawl into rotational movement." Lewis Opening Rep. ¶ 238. Mr. Anderson states that at "that level, nearly anything is an equivalent," but offers no contrary opinion regarding the relevant function. Anderson Rebuttal Rep. ¶ 193. Mr. Anderson is incorrect. Dose counters components can function in a variety of ways, mechanically or non-mechanically, or in combinations thereof. And within the category of

mechanical dose counter components, components can move linearly, rotationally, or in combinations thereof and can interact with different components. As I explain in my Opening Report in greater detail, Cipla's "units teeth ring" and the claimed "ratchet wheel" perform the same function in terms of which components of the device they interact with and how they do so. I therefore disagree with his criticism of this element of the analysis.

151. Mr. Anderson also fails to demonstrate any error in my analysis with respect to the function or results elements. With respect to these elements, Mr. Anderson refers back to his explanation of how Cipla's ANDA Product works, including his mistaken distinction between pulling and other forms of engagement. *See, e.g.*, Anderson Rebuttal Rep. ¶ 194 (citing Anderson Rebuttal Rep. § IX). Mr. Anderson also repeats his opinion that the "actuator pawl" and the "count pawl" cannot both refer to protrusions on the bottom of Cipla's "indexer." I discuss both of these criticisms in the Section above in connection with literal infringement of this limitation, and I disagree with them for the reasons stated previously. I incorporate that analysis as though fully set forth herein.

152. In sum, in my opinion, to the extent that Cipla's ANDA Product does not satisfy the requirements of this limitation literally under either side's proposed construction, it satisfies them under the doctrine of equivalents. Mr. Anderson's contrary opinions do not demonstrate otherwise.

b. Cipla's ANDA Product Comprises "an Actuator Comprising an Actuator Pawl Arranged to Engage with a First Tooth of the Ratchet Wheel, Wherein the Actuator Can Be Driven in Response to Canister Motion to Drive the Ratchet Wheel to Rotate" (Limitation 1B)

153. As I explain in my Opening Report, in my opinion, Cipla's ANDA Product satisfies this limitation, both literally and under the doctrine of equivalents. *See* Lewis Opening Rep. § VIII.C.1.d.2). With respect to this limitation, Mr. Anderson states only: "In my opinion,

the Cipla ANDA Product lacks an 'actuator pawl' and a 'ratchet wheel' for the reasons discussed in connection with Limitation 1A, and therefore does not meet this limitation literally or under the doctrine of equivalents." Anderson Rebuttal Rep. ¶ 197. I disagree with Mr. Anderson for the reasons explained in my Opening Report and above, which I incorporate by reference as though set forth fully herein. *See* Lewis Opening Rep. §§ VIII.C.1.d.1)-2); *supra* Section V.B.2.a.

c. Cipla's ANDA Product Comprises "a Count Pawl Arranged to Engage with a Second Tooth of the Ratchet Wheel, Wherein as the Ratchet Wheel Is Driven by the Actuator to Rotate, the Count Pawl Rides Along a Forward Surface of the Second Tooth and Resiliently Jumps over the Second Tooth" (Limitation 1C)

154. As I explain in my Opening Report, Cipla's ANDA Product satisfies this limitation literally and under the doctrine of equivalents, under both sides' proposed constructions. I incorporate that analysis as through set forth fully herein. *See* Lewis Opening Rep. § VIII.C.1.d.3).

155. In his Rebuttal Report, Mr. Anderson opines that Cipla's ANDA Product does not satisfy this limitation literally or under the doctrine of equivalents under either side's proposed construction because it does not comprise a "count pawl." *See* Anderson Rebuttal Rep. § XII.B.(i).c). As explained below in greater detail, I disagree with Mr. Anderson on each of these issues.

1) Literal Infringement

156. **Teva's Proposed Construction.** As explained above, I have been informed that Teva proposes that the term "count pawl" should be construed to mean "a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the ratchet wheel." *See supra* Section V.B.2. With respect to Teva's proposed construction, Mr. Anderson

states only that Cipla's "ANDA Product lacks a ratchet wheel and any structures acting as 'pawls', and therefore does not literally satisfy this limitation, under Plaintiffs' proposed construction." I disagree with Mr. Anderson for the reasons stated above in my Opening Report and above in connection with what he refers to as "Limitations 1A and 1B," and I incorporate that analysis as though fully set forth herein. *See* Lewis Opening Rep. §§ VIII.C.1.d.1)-2); *supra* Sections V.B.2.a-V.B.2.b. Thus, in my opinion, Cipla's ANDA Product satisfies this limitation under Teva's proposed construction.

157. **Defendants' Proposed Construction.** As explained above, I have been informed that Defendants have proposed to construe the term "count pawl" as "a pawl that is part of the dose counter, separate form an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel." *See supra* Section V.B.2.

158. With respect to Defendants' proposed construction, Mr. Anderson repeats his opinions that Cipla's "ANDA Product lacks a ratchet wheel and any structures acting as 'pawls'" and that the protrusions on the bottom of Cipla's "indexer" cannot satisfy the requirements of "both the actuator pawl and the count pawl." Anderson Rebuttal Rep. ¶¶ 205-06. I disagree with Mr. Anderson for the reasons stated above in my Opening Report and above in connection with what he refers to as "Limitations 1A and 1B," and I incorporate that analysis as though fully set forth herein. *See* Lewis Opening Rep. §§ VIII.C.1.d.1)-2); *supra* Sections V.B.2.a-V.B.2.b.

159. In addition, Mr. Anderson opines that Cipla's ANDA Product does not satisfy this limitation under Defendants' proposed construction based on what he characterizes as the plain meaning of the phrase "ride along a forward surface of the second tooth and resiliently jump over the second tooth." Anderson Rebuttal Rep. ¶¶ 207-11. Mr. Anderson opines that the protrusions on the bottom of Cipla's "indexer" do not "resiliently jump over the second tooth," but instead

engage and disengage with the inner teeth of Cipla's "units teeth ring." Anderson Rebuttal Rep. ¶ 208. I disagree with Mr. Anderson.

160. As above, Mr. Anderson's disagreement appears to be based on the conclusions that he draws from his explanation of how Cipla's ANDA Product functions rather than his or my explanation of that functioning. *See* Anderson Rebuttal Rep. ¶ 208. Although Mr. Anderson concludes that the protrusions on the bottom of Cipla's "indexer" do not "resiliently jump over the second tooth," he acknowledges that they "slide down" the inner teeth of Cipla's "units teeth ring" and return to their "rest position" during the operation of Cipla's ANDA Product. Anderson Rebuttal Rep. ¶ 208. I my opinion, the POSA would understand that process to involve "resiliently jumping" over the teeth on which they engage.

161. To support his contrary conclusion, Mr. Anderson opines that the plain meaning of "resiliently" is "a structure [sic] that quickly returns to its usual shape after being bent, stretched or pressed." Anderson Rebuttal Rep. ¶ 209. According to Mr. Anderson, the POSA would understand the phrase "resiliently jumping" over a tooth to mean that "as the wheel rotates, the tooth compresses or bends the count pawl, until it deforms enough to flex over the tooth, after which the count pawl maintains its original shape." Anderson Rebuttal Rep. ¶ 209 (citing Cambridge Dictionary Online; Webster's Online Dictionary). To support that assertion, Mr. Anderson cites various descriptions in the '156 Patent of an "anti-back drive" and usage of the term "resilient." *See* Anderson Rebuttal Rep. ¶ 209 (citing '156 Patent, 13:43-44, 14:16-18); *id.* ¶ 210 (citing '156 Patent, 3:15-16, 3:19-21, 4:40-45, 8:59-63, 9:1-3, 13:44, 14:67-15:1, 19:24, 19:41-43, 21:21-25). I disagree with Mr. Anderson's analysis.

162. As an initial matter, Mr. Anderson's definition of "resiliently" as "a structure [sic] that quickly returns to its usual shape after being bent, stretched or pressed" is grammatically

inconsistent with the '156 Patent's claims and written description and how the POSA would understand that term. Although Mr. Anderson's definition refers to "resiliently" in terms of a "structure," the term "resiliently" in the claim modifies the term "jumping," rather than any structural component. Thus, the POSA would understand that the term "resiliently" referred to the ability of the "count pawl" to quickly return from its displaced ***position*** within the system, not that that the "count pawl" ***itself*** compressed or deformed.

163. Indeed, even were the POSA to ignore the grammatical incompatibility of Mr. Anderson's definition of "resiliently" and the claim language (which, in my opinion, the POSA would not have done), the POSA would have understood the term to refer to the "count pawl's" movement within the system, not its compression or deformation. In my experience, mechanical engineers and others in the inhalation industry commonly use the term "resiliently" in terms of a component's position, rather than its position or shape. That broader understanding is further reflected in dictionary definitions. Indeed, although Mr. Anderson selectively cites two such definitions (Cambridge and Webster's), many dictionaries, including ones published by the same publishers that Mr. Anderson cites, define "resilient" or "resilience" in terms of the ability of a body to return from a displaced ***position***. *See, e.g.*, Atkins & Escudier, A Dictionary of Mechanical Engineering (1st ed. 2013) (Resilient: "The ability, on unloading, of a body to recover and spring back from its displaced condition."); Webster's Third New International Dictionary Unabridged 1932 (2002) (Resilient: "returning freely to a previous position, shape, or condition"); Webster's II New College Dictionary (1995) (Resilience: "The property of a material that enables it to resume its original shape or position after being bent, stretched, or compressed : ELASTICITY.").

164. The correct understanding of "resilient" in terms of the "count pawl's" ability to

recover from its displaced position is also consistent with the '156 Patent's usage of "resilient"—including the passages that Mr. Anderson relies upon. Indeed, as Mr. Anderson himself acknowledges, the '156 Patent uses those terms in connection with components, such as "pawls" and "anti-backdrive" elements that are generally constructed from rigid materials, or forces. *See, e.g.*, '156 Patent, 3:15-16, 3:19-21, 4:40-45, 8:59-63, 9:1-3, 13:43-44, 14:16-18, 14:67-15:1, 19:24, 19:41-43, 21:21-25. Nothing in those passages suggests that the term "resiliently" in the claims requires the "count pawl" to compress or deform. And in fact, to the extent that they describe components, those descriptions could equally apply to the movement of rigid objects.

165. In any event, even were Mr. Anderson's definition of "resiliently" properly applied to the claim language (which in my opinion, it is not), Mr. Anderson's argument fails on its own terms. As a matter of physics, all components, including those created from relatively rigid materials, compress or deform under pressure. The same is true of the protrusions on the bottom of Cipla's "indexer." *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawings); CIPLA-BDI_0803837-38 (Design Drawings). Thus, in my opinion, Cipla's ANDA Product satisfies this limitation even under Defendants' proposed construction and Mr. Anderson's definition of "resiliently."

166. In sum, in my opinion, Cipla's ANDA Product satisfies the requirements of this limitation, and Mr. Anderson's contrary opinions do not demonstrate otherwise.

2) Doctrine of Equivalents

167. Mr. Anderson also opines that Cipla's ANDA Product does not satisfy this limitation under the doctrine of equivalents. Anderson Rebuttal Rep. § XII.B.(i).c).2). Because Cipla's ANDA Product satisfies the requirements of this claim literally, Cipla's ANDA Product necessarily satisfies the requirements of this claim under the doctrine of equivalents.

Nevertheless, I address Mr. Anderson's arguments below for the sake of completeness. I disagree with each of Mr. Anderson's criticisms.

168. **Insubstantial Differences Test.** In my Opening Report, I opined that Cipla's ANDA Product satisfies this limitation under the insubstantial differences test. Mr. Anderson disagrees with this analysis. *See* Anderson Rebuttal Rep. § XII.B.(i).c).2).a). To the extent I understand Mr. Anderson's criticisms, Mr. Anderson appears to repeat arguments that he makes in connection with what he refers to as "Limitation 1A." First, Mr. Anderson states that (1) "there are substantial differences in this transfer of motion: in the patent the transfer is performed by pulling the teeth of the ring to force rotation." Anderson Rebuttal Rep. ¶ 214 (citing Anderson Rebuttal Rep. § XIII.B.(i).(a)). Second, Mr. Anderson states "while the count pawl as claimed is always resiliently engaged with the teeth of a ratchet wheel and prevents anti-back rotation, the ridges on the indexer engage and disengage entirely with the ridges of the units teeth ring and have no antiback function." Anderson Rebuttal Rep. ¶ 215. Third, Mr. Anderson repeats his assertion that "same structure cannot be both an actuator pawl and a count pawl while also satisfying a requirement that the actuator and count pawl." Anderson Rebuttal Rep. ¶ 216. In each case, Mr. Anderson appears to repeat arguments that he makes in connection with what he refers to as "Limitation 1A." I disagree with those criticisms for the reasons stated above, and I incorporate that analysis as though fully set forth herein. *See supra* Section V.B.2.a. Thus, I disagree with Mr. Anderson's opinion that Cipla's ANDA Product does not comprise an equivalent to this limitation under the insubstantial differences test.

169. **Function-Way-Result Test.** Mr. Anderson's criticisms of my analysis under the function-way-result test are similarly duplicative. *See* Anderson Rebuttal Rep. § XII.B.(i).c).2).b). In criticizing that analysis, Mr. Anderson repeats his argument that the

"count pawl" functions as a back-drive and that the protrusions on the bottom of what Cipla terms an indexer perform no equivalent function. Anderson Rebuttal Rep. ¶ 218. Mr. Anderson also repeats his argument that the protrusions on the bottom of Cipla's "indexer" cannot be equivalent to both the "actuator pawl" and the "count pawl." Anderson Rebuttal Rep. ¶ 219. Again, I disagree with Mr. Anderson's criticisms for the reasons stated above, and I incorporate that analysis as though fully set forth herein. *See supra* Section V.B.2.a. I therefore also disagree with Mr. Anderson's opinion that Cipla's ANDA Product does not comprise an equivalent to this limitation under the function-way-result test.

170. In sum, in my opinion, to the extent that Cipla's ANDA Product does not satisfy the requirements of this limitation literally under either side's proposed construction, it satisfies them under the doctrine of equivalents. Mr. Anderson's contrary opinions do not demonstrate otherwise.

d. Cipla's ANDA Product Comprises "a Dosage Indicator Associated with the Count Pawl" (Limitation 1D)

171. As I explain in my Opening Report, in my opinion, Cipla's ANDA Product satisfies this limitation. *See* Lewis Opening Rep. § VIII.C.1.d.4). With respect to this limitation, Mr. Anderson states only: "In my opinion, the Cipla ANDA Product lacks an 'count pawl' for the reasons discussed in connection with Limitation 1C, and therefore does not meet this limitation literally or under the doctrine of equivalents." Anderson Rebuttal Rep. ¶ 221. I disagree with Mr. Anderson for the reasons explained in my Opening Report and above, which I incorporate by reference as though set forth fully herein. *See supra* Lewis Opening Rep. § VIII.C.1.d.3)-4); *supra* Section V.B.2.c.

e. Cipla's ANDA Product Satisfies the Limitation "Wherein the Actuator Is Arranged to Define a First Reset Position in Which the Actuator Pawl is Brought into Engagement with the First Tooth" (Limitation 1E)

172. As I explain in my Opening Report, Cipla's ANDA Product satisfies this limitation literally, under Teva's proposed constructions. I further explain that, at a minimum, Cipla's ANDA Product satisfies this limitation under both sides' proposed constructions under the doctrine of equivalents. I incorporate that analysis as through set forth fully herein. *See* Lewis Opening Rep. § VIII.C.1.d.5).

173. In his Rebuttal Report, Mr. Anderson states that Cipla's ANDA Product does not infringe this limitation literally or under the doctrine of equivalents under either sides' proposed constructions. *See* Anderson Rebuttal Rep. § XII.B.(i).e). As explained below in greater detail, I disagree with Mr. Anderson's analysis.

1) Literal Infringement

174. **Teva's Proposed Construction.** As I explain above, I have been informed that Teva proposes that the term "first position" should be construed to mean "a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the canister fire configuration." *See supra* Section V.B.2.

175. With respect to literal infringement under Teva's proposed construction, Mr. Anderson states only: "As discussed above in connection with Limitation 1A, the Cipla ANDA Product lacks a ratchet wheel and any structures acting as an 'actuator pawl', and therefore does not literally satisfy this limitation under Plaintiffs' proposed construction." Anderson Rebuttal Rep. ¶ 227. I disagree with Mr. Anderson for the reasons stated above in my Opening Report and above in connection with what he refers to as "Limitation 1A," and I incorporate that analysis as though fully set forth herein. *See* Lewis Opening Rep. § VIII.C.1.d.1); *supra* Section V.B.2.a.

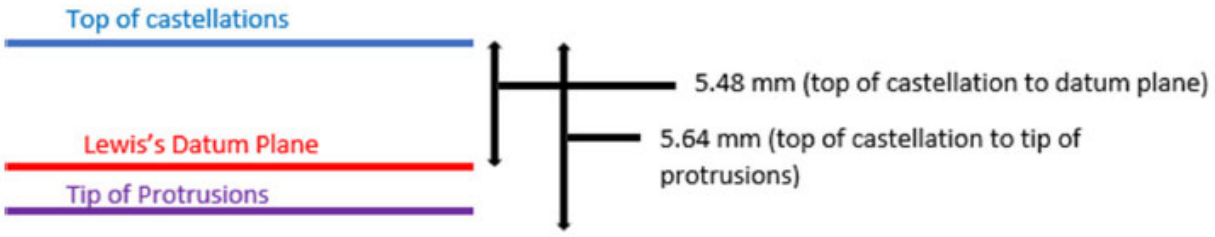
176. **Defendants' Proposed Construction.** As I explain above, I have been informed that Defendants' propose that the term "first position" should be construed to mean a

"configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel." *See supra* Section V.B.2.

177. With respect to literal infringement under Defendants' proposed construction, Mr. Anderson states: "As discussed above in connection with Limitation 1A, the Cipla ANDA Product lacks a ratchet wheel and any structures acting as an 'actuator pawl.'" Anderson Rebuttal Rep. ¶ 229. Mr. Anderson further states: "In addition, as discussed below in connection with Limitation 1F, the Cipla ANDA Product does not satisfy the required 'start configuration.'" Anderson Rebuttal Rep. ¶ 230. I disagree with Mr. Anderson for the reasons stated above in my Opening Report and above and below in connection with what he refers to as "Limitations 1A and 1F," and I incorporate that analysis as though fully set forth herein. *See* Lewis Opening Rep. §§ VIII.C.1.d.1), 6); *supra* Section V.B.2.a; *infra* Section V.B.2.f.

178. Mr. Anderson further opines that Cipla's ANDA Product does not satisfy this limitation based on a flawed analysis of certain experiments that I performed to support the opinions in my Opening Report. *See* Anderson Rebuttal Rep. ¶¶ 232-33.

179. Specifically, Mr. Anderson states that, based on my analysis of Cipla's ANDA Product, Cipla's "actuator pawl" (i.e., one or more of the protrusions on the bottom of what Cipla refers to as an "indexer") is beneath the "datum plane" passing through the "shoulder" of Cipla's "valve stem block" when the device is in the start position.



Anderson Rebuttal Rep. ¶ 232. Notably, however, although Mr. Anderson acknowledges the standard deviations associated with those values in his report, he does not account for them in his analysis. When those standard deviations are taken into account, Cipla's ANDA Product satisfies this limitation under Defendants' proposed construction.

180. Mr. Anderson further asserts that I ignore Defendants' proposed construction in my analysis. Anderson Rebuttal Rep. ¶ 233. It is unclear what basis he has for making that assertion. However, it appears to be based on his own, incorrect, assessment of Cipla's ANDA Product and my analysis of it. I therefore disagree with Mr. Anderson.

181. In sum, in my opinion, Cipla's ANDA Product satisfies the requirements of this limitation literally, and Mr. Anderson's contrary opinions do not demonstrate otherwise.

2) Doctrine of Equivalents

182. With respect to the doctrine of equivalents, Mr. Anderson provides only the following statement:

> Dr. Lewis's opinion on doctrine of equivalents is limited entirely to the "start position," which is not part of either party's construction in this limitation, except as a reference point that the first reset position is lower than the start position. It is undisputed that, in the Cipla ANDA Product, any position during the firing sequence is lower than the start position. As Dr. Lewis does not opine that the first reset position being above the datum plane is equivalent to being below, I understand that neither he nor Plaintiffs contend that the Cipla ANDA Product would infringe this limitation under the doctrine of equivalents if Defendants' construction is adopted.

Anderson Rebuttal Rep. ¶ 234.

183. As evidenced by Mr. Anderson's statement, Mr. Anderson's (and Cipla's) disagreement with my opinions on the doctrine of equivalents is based entirely on the parties' dispute over the term "start position," which does not appear in Asserted Claim 1 of the '156 Patent. Instead, that term is required only by Defendants' proposed construction of the term

"first position." Thus, I do not understand Mr. Anderson to disagree that, assuming Teva's proposed construction is correct, Cipla's ANDA Product satisfies this limitation under the doctrine of equivalents.

184. In sum, in my opinion, to the extent that Cipla's ANDA Product does not satisfy the requirements of this limitation literally under either side's proposed construction, it satisfies them under the doctrine of equivalents. Mr. Anderson's contrary opinions do not demonstrate otherwise.

f. Cipla's ANDA Product Satisfies the Limitation "Wherein the Actuator Is Further Arranged such that, During a Canister Fire Sequence, when the Actuator Is in a Second Position, Which Is After the First Reset Position and at a Canister Fire Configuration, the Medicament Canister Fires Medicament Before the Dose Counter Reaches a Count Configuration, and when the Actuator Is in a Third Position After the Second Position, the Count Pawl Resiliently Jumps over the Second Tooth and the Dose Counter Reaches the Count Configuration Whereby the Dosage Indicator Has Indicated a Count" (Limitation 1F)

185. As I explain in my Opening Report, Cipla's ANDA Product satisfies this limitation literally under Teva's proposed constructions. I further explain that, at a minimum, Cipla's ANDA Product satisfies this limitation under both sides' proposed constructions under the doctrine of equivalents. I incorporate that analysis as through set forth fully herein. *See* Lewis Opening Rep. § VIII.C.1.d.6).

186. In his Rebuttal Report, Mr. Anderson opines that Cipla's ANDA Product does not satisfy this limitation literally or under the doctrine of equivalents under either sides' proposed construction. *See* Anderson Rebuttal Rep. § XII.B.(i).f).

1) Literal Infringement

187. In his Rebuttal Report, Mr. Anderson opines that Cipla's ANDA Product does not satisfy this limitation literally under Defendants' proposed constructions of "canister fire

sequence," "canister fire configuration," or "count configuration." *See* Anderson Rebuttal Rep. § XII.B.(i).f).1). Mr. Anderson also opines that Cipla's ANDA Product does not satisfy the phrase a "third position after the second position." *See* Anderson Rebuttal Rep. ¶¶ 254-55. In my opinion, Mr. Anderson is incorrect.

188. **Defendants' Proposed Constructions.** As I explain above, and in my Opening Report, Defendants' proposed constructions for "canister fire sequence," "canister fire configuration," and "count configuration" contain a number of different requirements that do not appear in Asserted Claim 1, but only appear in Defendants' proposed constructions for those terms. I addressed these issues in analyzing Cipla's ANDA Product under the doctrine of equivalents, and I incorporate that analysis as though fully set forth herein. *See* Lewis Opening Rep. § VIII.C.1.d.6). As I explain in that analysis, at a minimum, Cipla's ANDA Product satisfies those limitations under the doctrine of equivalents.

189. In opining that Cipla's ANDA Product does not satisfy these limitations literally, Mr. Anderson refers in several instances to analysis of other limitations. *See, e.g.*, Anderson Rebuttal Rep. ¶ 239 ("As discussed above in connection with Limitation 1A, the Cipla ANDA Product lacks a ratchet wheel and any structures acting as 'pawls' . . ."), ¶¶ 245-47 ("As discussed in detail below, in my opinion a POSA would not draw the datum plane where Dr. Lewis has drawn it, even under Plaintiffs' construction. Rather, the only place that a POSA would have been able to draw the plane, in view of the specification and the Prosecution History, is where I have drawn it.") (citing Anderson Rebuttal Rep. § XIII.B.i.g), ¶¶ 252-53 ("As discussed above in connection with Limitation 1C, the Cipla ANDA Product . . . does not have a 'count pawl' and no structure 'resiliently jumps over a second tooth.'"). I disagree with Mr. Anderson for the reasons stated above in my Opening Report and above and below in connection

with what he refers to as "Limitations 1A and 1C" and the "datum plane" limitation, and I incorporate that analysis as though fully set forth herein. *See* Lewis Opening Rep. §§ VIII.C.1.d.1), 3), 7); *supra* Sections V.B.2.a, V.B.2.c; *infra* Section V.B.2.g.

190. I therefore disagree with Mr. Anderson's conclusions regarding whether Cipla's ANDA Product infringes these limitations under Defendants' proposed constructions.

191. **"Third Position After the Second Position."** Mr. Anderson also opines that Cipla's "ANDA Product does not meet this limitation, literally or under the doctrine of equivalents, under either Party's proposed construction because it does not have a 'third position ***after*** the second position.' It is clear that 'after' does not merely refer to a time point, as Dr. Lewis interprets it, but a location in the device." Anderson Rebuttal Rep. ¶ 254. According to Mr. Anderson: "The third position (the count position) must come ***locationally after***, or lower than the fire position. The '156 Patent makes clear that, this location is the key to their alleged improvement in accurate dose counting." Anderson Rebuttal Rep. ¶ 254 (citing'156 Patent, 5:4-8, 14:62-15:8, 15:2-11). I disagree with Mr. Anderson's opinions.

192. As an initial matter, I do not see any basis in Mr. Anderson's assertion that Asserted Claim 1, or either sides' proposed constructions of Asserted Claim 1, require that the second and third positions must be (as Mr. Anderson puts it) locationally different. Rather, as the '156 Patent, including the passages that Mr. Anderson relies upon, make clear, one challenge that the inventors (and others in the inhalation device industry) faced was developing a dose counter that accurately reported the number of doses remaining even though the device might fire before counting. Thus, the '156 Patent explains: "It has been found in the course of making the present invention that highly reliable counting can be achieved with the dose counter counting at or soon after the point at which canister fires." '156 Patent, 5:4-8. As that

explanation makes clear, the problem that the inventors faced was temporal rather than, strictly locational, as Mr. Anderson asserts. That explanation is consistent with my opinions, described in more detail in my Rebuttal Report, that the prior art taught away from devices that counted after firing. *See, e.g.*, Lewis Rebuttal Rep. § VI.B.2.a.2).a). I incorporate that analysis as though fully set forth herein.

193. Mr. Anderson's efforts to interpret the inventions more narrowly is without basis. To support his opinion, Mr. Anderson relies on part of a single paragraph describing an embodiment of the invention. *See* Anderson Rebuttal Rep. ¶ 254 (citing'156 Patent 14:62-15:8, 15:2-11). As the '156 Patent makes clear, however, that language ***does not*** describe the invention as recited in the claims. *See, e.g.*, '156 Patent, 11:6-11 ("The present invention may be carried out in various ways and preferred embodiment of a dose counter, inhaler and methods of assembly design and manufacture will now be described with reference to the accompanying drawings . . ."); 21:29-32 ("Various modifications may be made to the embodiment shown without departing from the scope of the invention as defined by the accompanying claims as interpreted under patent law."). Accordingly, in my opinion, the POSA would not have understood the "third position" and "second position" to be strictly locational.

194. In any event, Mr. Anderson is incorrect that my analysis shows or assumes that Cipla's "actuator" (i.e., what Cipla refers to as an "indexer") does not remain at a constant location during its contact with Cipla's ratchet wheel (i.e., what Cipla refers to as a "units teeth ring") and that it continues to move after Cipla's ANDA Product fires. *See, e.g.*, Lewis Opening Rep. ¶ 298, Ex. B, §§ B-C. Thus, Mr. Anderson's analysis fails even under his incorrect understanding of phrase "third position after the second position." That analysis further shows that, even assuming that Mr. Anderson is correct that Cipla's actuator is in the same location

during the second and third positions when assessed from the perspective of absolute location, it is in a different location when assessed from the perspective of total travel distance, which is the ultimate criterion with which the POSA would have been concerned. To the extent that does not demonstrate that Cipla's ANDA Product satisfies this limitation literally under Mr. Anderson's understanding of the term "third position after the second position," at a minimum, it demonstrates that Cipla's ANDA Product satisfies this limitation under the doctrine of equivalents. I address this issue in greater detail in the Section below.

2) Doctrine of Equivalents

195. In his Rebuttal Report, Mr. Anderson also criticizes my analysis of this limitation under the insubstantial differences and function-way-results tests. *See* Anderson Rebuttal Rep. § XII.B.(i).f).1). I disagree with Mr. Anderson's criticisms.

196. **Insubstantial Differences Test.** Mr. Anderson's criticisms of my analysis are unclear. Nevertheless, to the extent I understand them, Mr. Anderson appears to offer two such criticisms. First, Mr. Anderson opines that the differences between the claimed "start position" and Cipla's "start position" (which he terms Cipla's "rest position") are substantial because the "count pawl is such an important aspect of the invention that the claim recites its presence and its 'resilient jumping' twice." Anderson Rebuttal Rep. ¶ 256. He further states that, "the count pawl is the anti-back tooth of the invention," which "prevents backward rotation, which would cause inaccurate counting." Anderson Rebuttal Rep. ¶ 256. On those points, Mr. Anderson appears to repeat his arguments that one or more of the protrusions on the bottom of Cipla's ANDA Product cannot satisfy the requirements of a "count pawl." I disagree with Mr. Anderson for the reasons stated above in my Opening Report and above and below in connection with what he refers to as "Limitations 1A and 1C," and I incorporate that analysis as though fully set forth herein. *See* Lewis Opening Rep. §§ VIII.C.1.d.1), 3); *supra* Sections V.B.2.a, V.B.2.c.

197. Second, Mr. Anderson asserts that, whereas the '156 Patent explains that the inventors discovered that "highly reliable counting can be achieved with the dose counter counting ***at or soon after*** the point at which the counter fires," in Cipla's ANDA Product, "the count configuration completes on the return stroke." Anderson Rebuttal Rep. 257 (citing '156 Patent 5:4-8, 15:2-11). According to him, this "means that, the Cipla ANDA Product can record errors whereby it counts before or without reaching a configuration in which medicament fires," but that "the alleged invention the '156 Patent has the opposite problem—if not depressed sufficiently, it can fire without recording a count." Here, Mr. Anderson appears to repeat his argument that Cipla's dose counter counts before firing. I address this issue above, in connection with the '289 and '587 Patents, and I incorporate that analysis as though fully set forth herein. *See, e.g.*, *supra* Section V.A.1.a.2). In brief, Mr. Anderson is incorrect that Cipla's ANDA Product counts before firing, and my inspection of and experiments involving Cipla's ANDA Product demonstrate otherwise.

198. **Function-Way Result Test.** Mr. Anderson's criticisms of my function-way-results and insubstantial differences analysis are similarly repetitive. First, Mr. Anderson repeats his argument that Cipla's ANDA Product does not comprise a "count pawl" because one or more of the protrusions on the bottom of Cipla's "indexer" do not prevent backwards rotation. *See* Anderson Rebuttal Rep. ¶ 258. I disagree with Mr. Anderson for the reasons stated in my Opening Report and above in connection with what he refers to as "Limitations 1A and 1C," and I incorporate that analysis as though fully set forth herein. *See* Lewis Opening Rep. §§ VIII.C.1.d.1), 3); *supra* Sections V.B.2.a, V.B.2.c.

199. Second, Mr. Anderson states that the way in which the claimed "count configuration" and Cipla's "count configuration" improves count accuracy "is by having the

dose count occur after the fire configuration ***both*** temporally ***and*** locationally." Anderson Rebuttal Rep. ¶ 259. On this point, Mr. Anderson repeats his opinion that the '156 Patent's positional terms include a ***locational*** component. As I discuss above in connection with Mr. Anderson's analysis of the phrase "third position after the second position," Mr. Anderson is incorrect. Instead, the '156 Patent emphasizes that the relevant issue is the temporal sequence in which the device fires and counts. I incorporate that analysis as though fully set forth herein.

200. Nevertheless, even were Mr. Anderson's emphasis on location correct, which in my opinion, it is not, Cipla's ANDA Product at least satisfies Mr. Anderson's locational requirement under the doctrine of equivalents. Assuming, for argument's sake, that the proper analysis requires that the way in which the "count configuration" improve count accuracy "is by having the dose count occur after the fire configuration ***both*** temporally ***and*** locationally," Cipla's ANDA Product "count configuration" and its relationship to the other positions and configurations recited in Asserted Claim 1, including the canister fire configuration, functions in the same way because it has a locational component. Significantly, although Mr. Anderson assumes that any locational component must refer to absolute location, the POSA would understand that such a locational component could be framed in terms of total travel distance. Indeed, during my work in the inhalation device industry, we routinely measure components in terms of their total movement because it provides a more complete picture of their operation. Indeed, because the firing of a device can affect how the other components in the device operate, it is important to take total travel, rather than absolute location into account. Mr. Anderson's narrow focus on absolute location is inconsistent with how the POSA would have understood location, and I therefore disagree with his analysis regarding that element.

201. In sum, in my opinion, to the extent that Cipla's ANDA Product does not satisfy

the requirements of this limitation literally under either side's proposed construction, it satisfies them under the doctrine of equivalents. Mr. Anderson's contrary opinions do not demonstrate otherwise.

g. Cipla's ANDA Product Satisfies the Limitation "Wherein, in the Canister Fire Configuration, the Actuator Pawl Is Below a Datum Plane Which Passes Through a Shoulder of a Valve Stem Block Configured to Receive the Medicament Canister" (Limitation 1G)

202. As I explain in my Opening Report, Cipla's ANDA Product satisfies this limitation literally under Teva's proposed constructions. I further explain that, at a minimum, Cipla's ANDA Product satisfies this limitation under both sides' proposed constructions under the doctrine of equivalents. I incorporate that analysis as through set forth fully herein. *See* Lewis Opening Rep. § VIII.C.1.d.7).

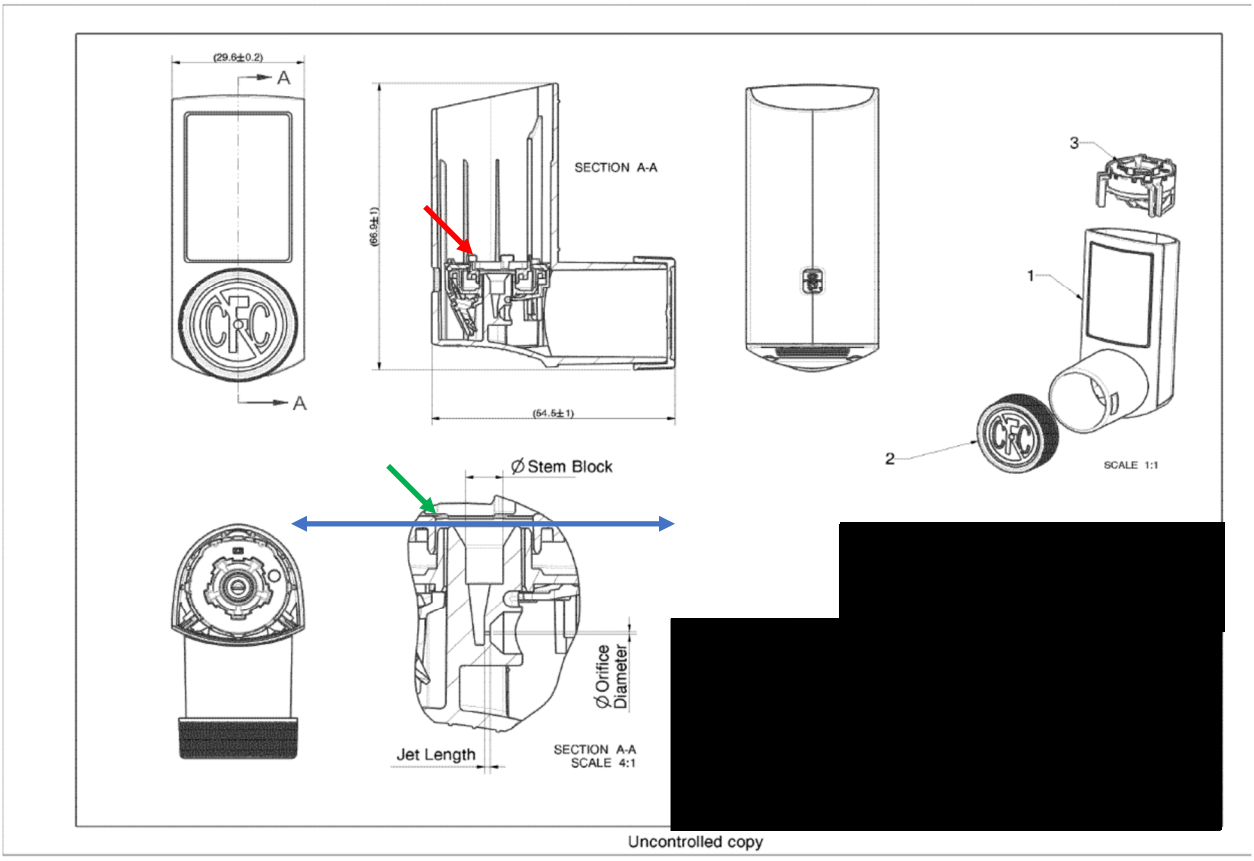
203. Mr. Anderson opines that Cipla's ANDA Product does not satisfy this limitation literally or under the doctrine of equivalents under each side's proposed construction. *See* Anderson Rebuttal Rep. § XII.B.(i).g). As I explain below in greater detail, I disagree with Mr. Anderson's conclusions.

1) Literal Infringement

204. As explained above, I have been informed that Teva has proposed that the "datum plane limitation" should be construed to mean "a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister." I have been informed that Defendants have proposed to "plane passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet." *See supra* Section V.B.2.

205. With respect to both proposed constructions, Mr. Anderson states that "there is only one place in the Cipla ANDA Product that a POSA could reasonably draw the datum plane in view of the specification and prosecution history" and, therefore, his "opinion remains the same under either construction." Anderson Rebuttal Rep. ¶ 265. I disagree.

206. In my Opening Report, I offered the opinion that Cipla's ANDA Product satisfies this limitation based on my opinion that Cipla's ANDA Product has a "datum plane [blue arrow] which passes through a shoulder [green arrow] of a valve stem block [red arrow]," as depicted in the diagram reproduced below.



Confidential CIPLA-BDI_0803837

Lewis Opening Rep. ¶ 316 (citing CIPLA-BDI_0803837-38 (Design Drawings)); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579 (Design Drawings).

207. Mr. Anderson disagrees with this analysis on the basis that the "shoulder" that I identify is at "the very top (e.g., the head) of the valve stem block" and therefore cannot be a "shoulder." Anderson Rebuttal Rep. ¶ 266. I disagree.

208. Contrary to Mr. Anderson's assertion, the POSA would understand that a "shoulder" could be located at the "top" of the valve stem block. Mr. Anderson draws a distinction between the "shoulder" of a component and the "head" of a component, which has no basis in how the POSA would understand the term "shoulder" or ordinary usage. For example, the POSA (like other English speakers) would be familiar with the phrases "shoulder of the mountain" and "shoulder of the hill" which refer to the shoulder-like portions of a mountain or hill near the top. *See, e.g.*, Webster's Third New International Dictionary of the English Language Unabridged 2104 (2002) ("the part of a hill or mountain near the top"). The POSA would also understand (like other English speakers) that the term "shoulder" can be properly used in connection with words that do not have a "head" (or at least to the extent that they have one, a "head" that has a very different meaning than the one that Mr. Anderson ascribes), like a road or river. *See id.* Mr. Anderson's purported distinction between "head" and "shoulder is without basis in the proper usage of that term.

209. None of Mr. Anderson's arguments support a different conclusion. First, Mr. Anderson asserts that the "POSA would not expect the datum plane to be at the top of the valve stem block as moving the datum plane further from the point at which medicament is expelled worsens the tolerance control in dose counters, leading to increased errors. Given that the '156

Patent is allegedly directed to increasing tolerances and reducing count errors, a POSA would not expect any construction of datum plane line to encompass positions that increase errors." Anderson Rebuttal Rep. ¶ 267. I do not understand what information Mr. Anderson is relying on as the basis for this opinion, but it is inconsistent with my experience. In my experience working with medicament canisters, valve stems, and valve stem blocks, I and my colleagues frequently use the term "shoulder" in the manner that I use it in my reports with reference to shoulders similar to the one depicted in Cipla's ANDA Product.

210. Mr. Anderson's contrary opinion (for which he provides no citation) appears to be conflate the issue of what the POSA would consider to be a "shoulder" with what factors contribute to dose counter accuracy, which are conceptually unrelated. Mr. Anderson is further incorrect that the placement of a datum plane at the top of the valve stem block would increase dose counter errors.

211. Second, Mr. Anderson asserts that Cipla's ANDA Product cannot satisfy the requirements of this limitation because the '156 Patent "describes the datum plane as 'a datum ***at which the canister fires medicament.***" Anderson Rebuttal Rep. ¶ 267 (quoting '156 Patent, 4:59). In fact, and in my opinion, the '156 Patent supports (including the passage that Mr. Anderson relies upon), supports that conclusion. As I explain in my Opening Report in greater detail, the '156 Patent as a whole describes the datum plane as a reference plane for measuring the height of the actuator pawl in the first reset position, canister fire configuration, and count configuration. *See* '156 Patent, 13:42-15:33; 17:24-61 Figs. 9, 10A-10F, 11, 14; Lewis Opening Rep. § VIII.C.1.d.7). Thus, the POSA would not understand it to be tethered to a particular location in the valve stem block, as Mr. Anderson asserts.

212. Furthermore, even were the POSA to consider the passage that Mr. Anderson

relies upon in isolation, which the POSA would not have done, the POSA would not have agreed with his conclusions regarding the location of the valve stem block. Tellingly, unlike Asserted Claim 1, that passage does not use the term "shoulder." Moreover, the passage expressly states that it describes only an "aspect" (i.e., embodiment) of the invention. *See* '156 Patent, 4:46 ("According to another aspect of the present invention . . ."). Consequently, the POSA would not, as Mr. Anderson does, infer from this passage that a "shoulder" or "datum plane" passing through that shoulder would necessarily be located at the bottom of the valve stem block. To the contrary, the POSA would have understood from that language that, in the context of Asserted Claim 1, the "shoulder" and "datum plane" could be located elsewhere, including where Cipla's "shoulder" is located in Cipla's valve stem block.

213. Third, Mr. Anderson asserts that the '156 Patent's prosecution history supports his opinion. *See* Anderson Rebuttal Rep. ¶ 268 (citing '156 Patent Prosecution History, Applicant Response 2, 7 (Mar. 13, 2018); Notice of Allowance 3 (May 31, 2018); Bowman, Figs. 2, 9). I have reviewed the prosecution history and references that Mr. Anderson cites, and I disagree with his conclusions. In my opinion, nothing in that prosecution history demonstrates that the applicant clearly and unmistakably disclaimed a device in which the "shoulder of the valve stem block" or "datum plane" passing through it was in the same or equivalent location as the "shoulder" and "datum plane in Cipla's ANDA Product. Nor does that prosecution history demonstrate that the "shoulder" and "datum plane in Cipla's ANDA Product do not qualify as such.

214. To support his opinions regarding the '156 Patent's prosecution history, Mr. Anderson relies on a flawed analysis of the Examiner's findings regarding Bowman.

215. On March 13, 2018, during prosecution of the application that issued as the '156

Patent, applicant amended the then-pending claims to add the phrase "wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister." *See* '156 Patent Prosecution History, Applicant Response 2 (Mar. 13, 2018). The applicant further stated: "Bowman does not disclose each and every element of claim 1. In particular, Bowman does not disclose wherein, in the canister fire configuration, the actuator pawl is below the datum plane as claimed." '156 Patent Prosecution History, Applicant Response 7 (Mar. 13, 2018).

216. On May 31, 2018, the Examiner issued a Notice of Allowance. In that notice, the Examiner stated:

> Claims 1, 2 and 4-14 are allowed.
>
> The following is an examiner's statement of reasons for allowance: The prior art fails to teach or fairly suggest, in the context of all other elements of claim, the limitation, "wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister."
>
> The examiner performed a careful comparison of figure 2 of Bowman with instant figure 9, which shows the now claimed 'datum plane', and the 'shoulder of a valve stem block configured to receive the medicament canister'. From this it appears that in Bowman, this datum plane is somewhat below contacting portion of the drive means 50. The actuator pawl of Bowman is above the plane which passes through a shoulder of a valve stem block configured to receive the medicament canister as it advances the counter wheel.

'156 Patent Prosecution History, Notice of Allowance (May 31, 2018).

217. I have carefully reviewed the '156 Patent and Bowman, including Figure 9 of the '156 Patent and Figure 2 of Bowman. I reproduce those figures below.

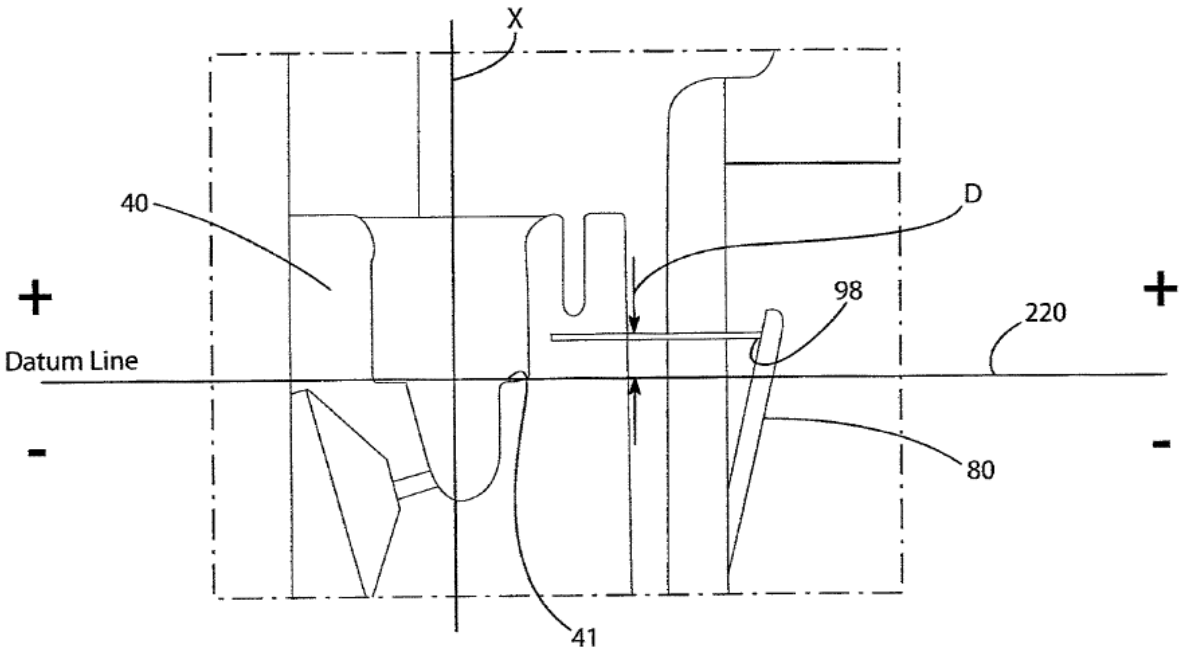
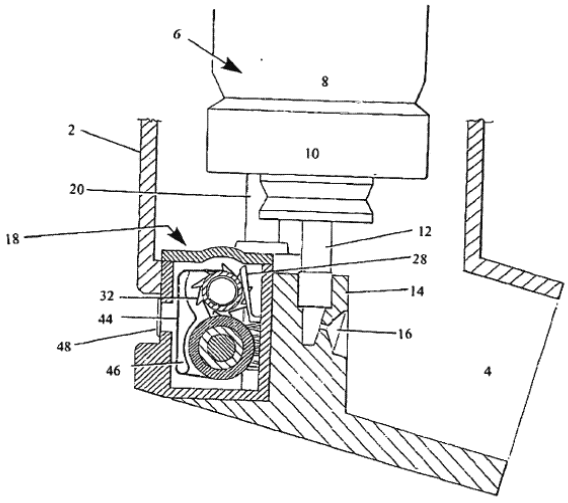


FIG. 9

'156 Patent, Fig. 9.



(Prior art)

Fig. 2

Bowman, Fig. 2.

218. In my opinion, nothing in those figures supports Mr. Anderson's conclusions regarding the prosecution history.

219. Mr. Anderson asserts, based on what he purports to be his own analysis of Bowman, that if the Examiner had "instead draw the datum plane where Dr. Lewis contends (shown with a blue line), at the top of the valve stem block, then Bowman in fact discloses an actuator pawl ***below*** the plane which passes through a shoulder of a valve stem block configured to receive the medicament canister as it advances the counter wheel."

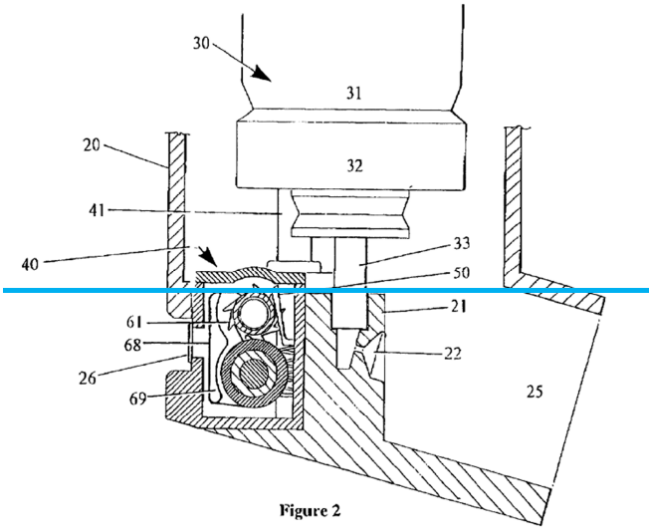


Figure 2

Anderson Rebuttal Rep. ¶ 272 (citing Bowman, Fig. 2).

220. I disagree with Mr. Anderson's analysis. Among other things, Bowman does not mention the term "actuator pawl," "datum plane," "shoulder," "valve stem block"; identify where those components are located in Figure 2; or explain how the location of an "actuator pawl" changes over time, much less how it changes relative to a "datum plane passing through a shoulder of the valve stem block" during the device's operation. *See, e.g.*, Bowman, 7:9-10, 7:25-8:30. Thus, as the Examiner correctly found, Bowman does not disclose this limitation.

221. Mr. Anderson concludes that the Examiner believed that Bowman disclosed a "shoulder" and "datum plane" at a location he depicts in red from the Examiner's statement that "this datum place is somewhat below contacting portion of the drive means 50." Anderson

Rebuttal Rep. ¶ 271. I reproduce Mr. Anderson's figure depicting what he believes to be the Examiner's identification of Bowman's "datum plane" below.

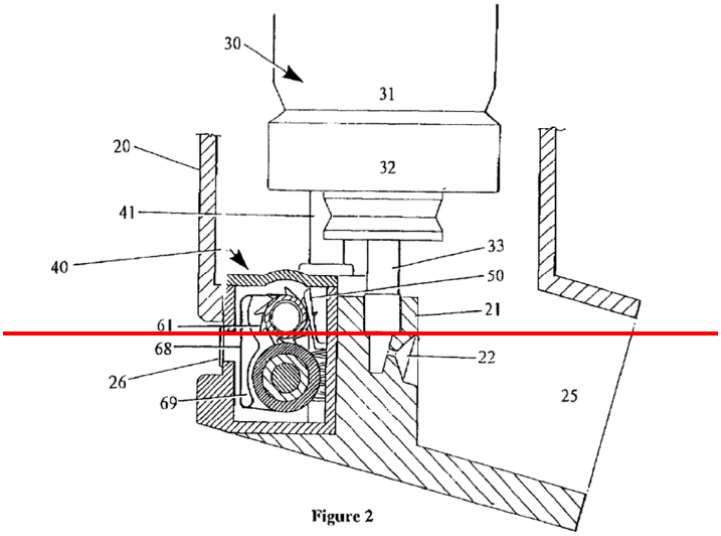


Figure 2

Anderson Rebuttal Rep. ¶ 271 (citing Bowman, Fig. 2).

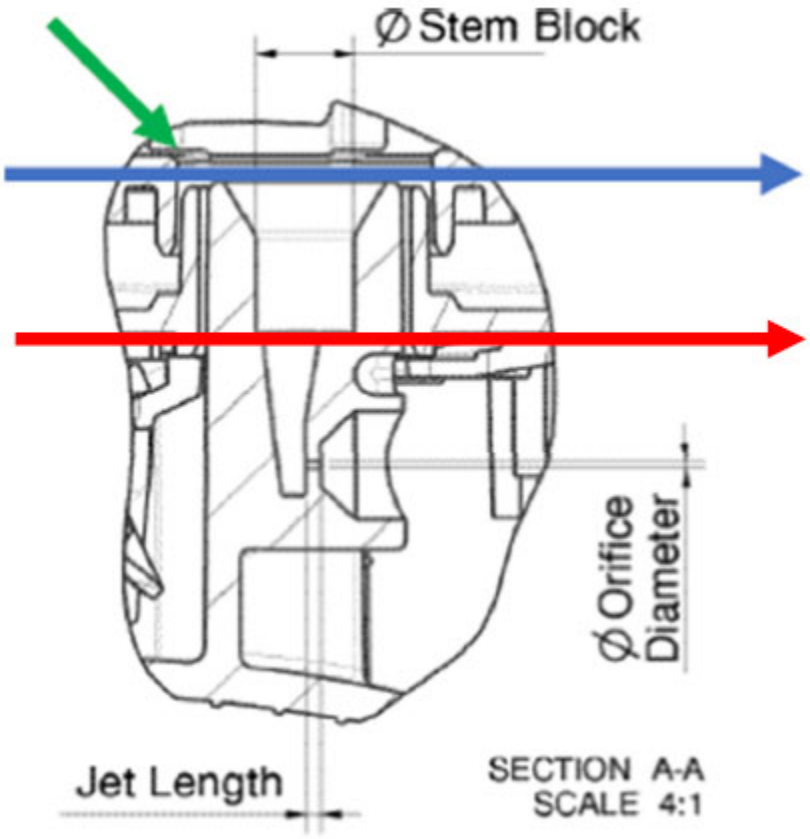
222. I disagree with Mr. Anderson's analysis of Bowman and the Examiner's statement. Nothing in the Examiner's statement suggests that the Examiner considered Bowman's "shoulder" or "datum plane" to be at the location Mr. Anderson depicts. Nor is that statement contrary to my analysis of Cipla's ANDA Product or Bowman.

223. Indeed, nothing in the Examiner's statement suggests that what the Examiner considered to be the "contacting portion of the drive means 50" in Bowman is below what he identifies as the application of "my" "datum plane" to Bowman. Nor, even assuming that Mr. Anderson is correct, does it suggest that the "datum plane" must be instead located at the position he assumes.

224. I therefore disagree with Mr. Anderson's analysis of the prosecution history.

225. After rejecting my analysis regarding the location of the "shoulder" and the "datum plane" passing through that "shoulder," Mr. Anderson identifies what he believes to be

the relevant "shoulder" and "datum plane." (red line).



Anderson Rebuttal Rep. ¶ 274. He proceeds to opine that Cipla's ANDA Product does not satisfy this limitation under that shoulder. *See* Anderson Rebuttal Rep. ¶¶ 274-83.

226. Mr. Anderson's non-infringement analysis is predicated entirely on his mistaken views that Cipla's valve stem block can only have one shoulder and that my analysis of Cipla's "shoulder" and the "datum plane" passing through it are incorrect. As I explain in my Opening Report and above, Mr. Anderson is incorrect as to those issues. I therefore disagree with his conclusions.

2) Doctrine of Equivalents

227. Mr. Anderson opines that Cipla's ANDA Product does not satisfy the requirements of this limitation based on prosecution history estoppel. *See* Anderson Rebuttal

Rep. § XII.B.(i).g).2). He also criticizes my analysis under the insubstantial differences and function-way-results tests. *See* Anderson Rebuttal Rep. § XII.B.(i).g).3). In each case, Mr. Anderson refers back to his analysis regarding literal infringement and the location of the "datum plane passing through a shoulder of the valve stem block." As I explain above in the previous Section, I disagree with Mr. Anderson on each of these issues. I incorporate that analysis as though fully set forth herein. In brief, Mr. Anderson does not demonstrate that the applicant clearly and unmistakably disclaimed a device in which the "shoulder of the valve stem block" or "datum plane" passing through it was in the same or equivalent location as the "shoulder" and "datum plane in Cipla's ANDA Product. And Mr. Anderson's analysis of that limitation is not consistent with the '156 Patent, the prosecution history, or how the POSA would have understood those terms.

228. Additionally, Mr. Anderson asserts that my analysis under the insubstantial differences and function-way-results tests is incorrect because I analyzed the location of a shoulder rather than the term "below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister." *See* Anderson Rebuttal Rep. ¶¶ 287-88. He is incorrect. As reflected by Mr. Anderson's own lengthy discussion of the term "shoulder," the parties' disagreement over the "datum plane" limitation is based on the location of the "shoulder" through which the "datum plane" passes. Mr. Anderson does not offer any explanation as to how I supposedly ignored the other requirements of that limitation or how those requirements would affect the analysis.

229. In sum, in my opinion, to the extent that Cipla's ANDA Product does not literally satisfy this limitation, it does so under the doctrine of equivalents. Mr. Anderson's opinions do not demonstrate otherwise.

3. Claims 9, 11

230. Asserted Claims 9 and 11 depend from Asserted Claim 1. As I explain in my Opening Report, Cipla's ANDA Product satisfies the requirements of these claims, both literally and under the doctrine of equivalents, under both sides' proposed constructions. With respect to each of these claims, Mr. Anderson states only that Cipla's ANDA Product "does not infringe this claim literally, or under the doctrine of equivalents, for the same reasons set forth in connection with Claim 1." Anderson Rebuttal Rep. ¶¶ 293, 295. I disagree with Mr. Anderson for the reasons explained in connection with Asserted Claim 1 and in my Opening Report, which I incorporate by reference as though set forth fully herein. *See* Lewis Opening Rep. §§ VII.C.1-3; *supra* Section V.B.2.

4. Claim 12

231. Asserted Claim 12 recites: "[A]n inhaler as claimed in claim 11 in which the body includes a canister-receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator."

232. As stated in my Opening Report, I have been informed that the parties have proposed different constructions for the term "separate counter chamber." I have been informed that Teva proposes that the term should be construed according to its plain and ordinary meaning in view of the claims, specification, and prosecution history, to mean "a separate chamber of the inhaler in which the dose counter is located." I have been informed that Defendants propose that the term should be construed to mean a "discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in

which the dose counter is located." *See supra* Section V.B.2. I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue.

233. As I explain in my Opening Report, in my opinion, Cipla's ANDA Product satisfies the requirements of this claim, both literally and under the doctrine of equivalents, under both parties' proposed constructions of the term "separate counter chamber." I incorporate that analysis as though set forth fully herein. *See* Lewis Opening Rep. § VII.C.4.

234. In his Rebuttal Report, Mr. Anderson opines that Cipla's ANDA Product does not satisfy the requirements of this claim, literally or under the doctrine of equivalents, under either side's proposed construction. Anderson Rebuttal Rep. § XII.B.(v). As I explain below in greater detail, I disagree with Mr. Anderson on each of these issues.

a. Literal Infringement

235. **Teva's Proposed Construction.** In his Rebuttal Report, Mr. Anderson opines that Cipla's ANDA Product does not literally satisfy the requirements of this claim under either side's proposed construction because, in his view, Cipla's ANDA Product does not literally comprise "a "***body of the inhaler having wall surfaces separating*** the canister receiving portion and the counter chamber." Anderson Rebuttal Rep. ¶ 299. I disagree with Mr. Anderson. As I explain in my Opening Report, Cipla's ANDA Product literally satisfies this requirement under both side's proposed constructions because when Cipla's ANDA Product is assembled, Cipla's dose counter—including its dose counter body, ratchet wheel, and actuator—is located in a separate chamber of the inhaler body, which is separated from the canister-receiving portion of the inhaler body by the inner wall surfaces and the lid (which together comprise the claimed inner wall surfaces). *See* Lewis Opening Rep. § VII.C.4.

236. In his Rebuttal Report, Mr. Anderson offers two reasons why, in his view, Cipla's inner wall surfaces and lid do not satisfy this requirement. First, Mr. Anderson opines that

Cipla's body "does not have wall surfaces separating the inhaler into any portions. Rather, in the Cipla ANDA Product, the dose counter, in its housing, is inserted and removed as a whole from the inhaler. And, to the extent the dose counter is separated from canister receiving portion of the inhaler, it is separated by the housing with a lid, as shown below, not by walls of the body." Anderson Rebuttal Rep. ¶¶ 300-01 (citing Cipla Samples). Second, Mr. Anderson opines that Cipla's inner wall surfaces and lid do not separate the Cipla's "separate counter chamber" from the "canister-receiving portion of the inhaler" because Cipla's "lid does not contact the inner walls to be able to form a chamber or cavity." Anderson Rebuttal Rep. ¶ 302. I disagree with Mr. Anderson on both points.

237. First, Mr. Anderson is incorrect that Cipla's housing, not Cipla's inner wall surfaces and lid, separate Cipla's "separate dose counter chamber" from the "canister-receiving portion of the inhaler." When Cipla's ANDA Product is assembled, Cipla's canister is located above Cipla's dose counter; thus, Cipla's inner wall surfaces and lid, not Cipla's housing, separate Cipla's "separate dose counter chamber" from the "canister-receiving portion of the inhaler." *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawing); CIPLA-BDI_0803837-38 (Design Drawings); Lewis Opening Rep. § III.

238. Additionally, even were Mr. Anderson's analysis of Cipla's housing, inner wall surfaces, and lid correct (which, in my opinion, it is not), his conclusion—that Cipla's housing, not Cipla's inner wall surfaces and lid separate Cipla's "separate dose counter chamber" from the "canister-receiving portion of the inhaler"—relies on a false dichotomy. Even assuming, for argument's sake, that Cipla's housing separates certain elements of Cipla's dose counter from the "canister-receiving portion of the inhaler," Cipla's inner wall surfaces and lid ***also*** perform this

function. Mr. Anderson's conclusion that Cipla's inner wall surfaces and lid do not separate Cipla's dose counter from Cipla's "canister-receiving portion of the inhaler" does not follow from his premise that Cipla's housing does so. I therefore disagree with Mr. Anderson that the presence and/or function of Cipla's housing means that Cipla's ANDA Product does not satisfy this limitation.

239. Second, Mr. Anderson's argument that Cipla's "lid does not contact the inner walls to be able to form a chamber or cavity" relies on his mistaken assumption that, to "separate" the "separate dose counter chamber" from the "canister-receiving portion of the inhaler," the components that comprise the claimed inner wall surfaces (here, Cipla's inner wall surfaces and lid) must come into contact or otherwise create a perfect seal. Nothing in the claim language or Teva's proposed construction implies this requirement, and indeed, such a requirement would be inconsistent with the claim language, which requires the wall surfaces to have a "communication aperture" through which an "actuation member" extends. As I explain in my Opening Report and above, in my opinion, Cipla's inner wall surfaces and lid create such a "separate counter chamber" regardless of whether they contact each other. *See* Lewis Opening Rep. § VII.C.4.

240. Thus, in my opinion, Cipla's ANDA Product satisfies the requirements of this claim under Teva's proposed construction. Mr. Anderson's contrary opinions do not demonstrate otherwise.

241. **Defendants' Proposed Construction.** In analyzing this claim under Defendants' proposed construction, Mr. Anderson refers back to his analysis of the claim under Teva's proposed construction. *See* Anderson Rebuttal Rep. ¶ 304 (citing Anderson Rebuttal Rep. ¶¶ 300-03). I disagree with Mr. Anderson for the reasons stated above, in the previous section,

and I incorporate that analysis as through fully set forth herein.

242. In brief, Mr. Anderson's analysis under Defendants' proposed construction—which requires the "separate counter chamber" to be a "discrete space or cavity defined by the main surface of the inner walls and the inner wall"—repeats his mistaken assumption that the inner wall surfaces and lid must create a perfect seal separating the counter chamber from the rest of the inhaler. Again, nothing in the claim language or Defendants' proposed construction implies such a requirement; and in fact, such a requirement would be inconsistent with the claim language, which requires the inner wall surfaces to have a "communication aperture." Correctly understood, Cipla's inner wall surfaces and lid define such a chamber regardless of whether they contact each other. *See* Lewis Opening Rep. § VII.C.4.

243. Thus, in my opinion, Cipla's ANDA Product also satisfies the requirements of this claim under Teva's proposed construction. Again, Mr. Anderson's contrary opinions do not demonstrate otherwise.

b. Doctrine of Equivalents

244. Mr. Anderson further opines that Cipla's ANDA Product cannot satisfy the requirements of this claim under the doctrine of equivalents because application of the doctrine of equivalents to Cipla's ANDA Product would "vitiate" the term "wall surfaces." Anderson Rebuttal Rep. ¶ 306. Mr. Anderson further criticizes the opinions in my Opening Report under the insubstantial differences and function-way-results tests. Anderson Rebuttal Rep. ¶¶ 307-09. Because Cipla's ANDA Product satisfies the requirements of this claim literally, Cipla's ANDA Product necessarily satisfies the requirements of this claim under the doctrine of equivalents. Nevertheless, I address Mr. Anderson's arguments below for the sake of completeness. I disagree with each of Mr. Anderson's criticisms.

245. **"Vitiation."** To the extent that vitiation is a proper basis for asserting non-

infringement under the doctrine of equivalents, Mr. Anderson is incorrect that the application of the doctrine would vitiate the term "body of the inhaler having wall surfaces separating the canister receiving portion and the counter chamber." Anderson Rebuttal Rep. ¶ 306. Once again, Mr. Anderson's analysis relies on the mistaken assumption that, for the inner wall surfaces and their equivalents to "separate" the separate counter chamber, they must form a perfect seal. As I explain above, that view is incorrect, and the claim language and the parties' proposed constructions do not imply such a requirement. I therefore disagree with Mr. Anderson.

246. **Insubstantial Differences Test.** Mr. Anderson's analysis under the insubstantial differences test is likewise incorrect. Mr. Anderson offers two purported differences between Cipla's ANDA Product and the claim language. First, Mr. Anderson states that "there is no space created by 'Cipla's inner wall surfaces and lid'" because Cipla's "lid does not touch the inner wall surfaces of the inhaler body." Anderson Rebuttal Rep. ¶ 307. Second, Mr. Anderson states that, purportedly, "the 'inhaler body' of the Cipla ANDA Product is not contained in a separate counter chamber," but instead "the housing containing the dose counter parts is contained in the inhaler body." Anderson Rebuttal Rep. ¶ 307. As I explain above in connection with literal infringement and vitiation, Mr. Anderson is mistaken with respect to both of these purported differences. I therefore again disagree for the reasons stated above.

247. **Function-Way-Result Test.** Mr. Anderson's analysis under the function-way result test is incorrect for similar reasons. Once again, Mr. Anderson relies on the mistaken assumptions that Cipla's "inner wall surfaces and lid" "do not connect and therefore do not form a chamber" and Cipla's "housing containing the dose counter parts is contained in the inhaler body." Anderson Rebuttal Rep. ¶ 308. I disagree with those assumptions for the reasons stated above.

248. Mr. Anderson further states that the chamber, space, or cavity created by Cipla's housing and lid "does not perform substantially the same function as the separate counter chamber in the [claim in] substantially same way to obtain substantially the same result" because the claim requires "that the chamber be an integrated part of the inhaler body, while the Cipla ANDA Product uses a separate housing that can be entirely removed from the inhaler body." Anderson Rebuttal Rep. ¶ 308. Mr. Anderson's analysis suffers from multiple flaws.

249. As an initial matter, although Mr. Anderson asserts that this purported difference is independent from the others he identifies, in fact, it relies on his mistaken assumption that Cipla's housing is part of Cipla's dose counter. Again, I disagree with that assumption for the reasons stated above.

250. Regardless, whether or not Cipla's housing or other components can be removed from the inhaler does not demonstrate non-infringement under the proper function-way result analysis. I do not understand Mr. Anderson to contest that the proper analysis involves a determination of whether Cipla's inner wall surfaces and lid "perform the function of separating the canister receiving portion of the inhaler body from the sensitive elements of the dose counter, including the ratchet wheel and inhaler body, by way of creating a separate space within the inhaler body, to obtain the result of protecting the sensitive elements of the dose counter." Anderson Rebuttal Rep. ¶ 308 (quoting Lewis Opening Rep. ¶ 349). Even assuming, for argument's sake, that Mr. Anderson's analysis of Cipla's ANDA Product is correct, Cipla's inner wall surfaces and lid would still satisfy these elements. Thus, Mr. Anderson's argument fails in any event.

251. In sum, in my opinion, to the extent that Cipla's ANDA Product does not satisfy the requirements of this claim literally under either side's proposed construction, it satisfies the

requirements of this claim under the doctrine of equivalents. Once again, Mr. Anderson's contrary opinions do not demonstrate otherwise.

252. In passing, Mr. Anderson reasserts his opinion that Asserted Claim 12 "is structurally impossible and indefinite." Anderson Rebuttal Rep. ¶ 297. I address these opinions my Rebuttal Report. *See* Lewis Rebuttal Rep. § VI.B.3.

5. Claim 13

253. Asserted Claim 13 recites: "The dose counter of claim 1, wherein the shoulder is a bottom surface within the value stem block and the datum plane is perpendicular to a direction of the movement of the medicament canister." As I explain in my Opening Report, in my opinion, Cipla's ANDA Product satisfies the requirements of this claim, at a minimum, under the doctrine of equivalents under both sides' proposed constructions. In response, Mr. Anderson opines that Cipla's ANDA Product "does not infringe this claim literally, or under the doctrine of equivalents, for the same reasons set forth in connection with Claim 1." Anderson Rebuttal Rep. ¶ 311. I disagree with Mr. Anderson for the reasons explained in my Opening Report and above, which I incorporate by reference as though set forth fully herein. *See supra* Lewis Opening Rep. §§ VII.C.1, VII.C.5; *supra* Section V.B.2.

254. Mr. Anderson further states that in my Opening Report, I made "little attempt to opine this claim is infringed, literally or under the doctrine of equivalents" and that my analysis was "devoid of identification of the claimed datum plane and is devoid of any evidence that the alleged count pawl is below claimed datum plane." Anderson Rebuttal Rep. ¶ 312. I disagree. As I explain in my Opening Report, the additional requirements of Asserted Claim 13 mirror Defendants' proposed construction of the term "datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister," which appears in Asserted Claim 1. Lewis Opening Rep. § VII.C.5. Because, in my opinion, Cipla's ANDA Product

satisfies the requirements of that limitation at a minimum, under the doctrine of equivalents, Cipla's ANDA Product satisfies the requirements of Asserted Claim 13 for the same reasons. Indeed, despite Mr. Anderson's complaints, Mr. Anderson appears to acknowledge this in stating that my analysis of Asserted Claim 13 relies on my "analysis of claim 1." Anderson Rebuttal Rep. ¶ 312. Mr. Anderson proceeds to summarize his criticisms of my analysis of Asserted Claim 1, which I disagree with for the reasons stated in my Opening Report and above, which I incorporate by reference as though set forth fully herein. *See supra* Lewis Opening Rep. §§ VII.C.1, VII.C.5; *supra* Section V.B.2.

6. Teva's Equivalents Theories Do Not Ensnare the Prior Art.

255. In his Rebuttal Report, Mr. Anderson refers back to the opinions in his Opening Report and states that "to the extent that Dr. Lewis contends that the Cipla ANDA Product meets any claim of the '156 Patent under the doctrine of equivalents, such expansion of the claims improperly ensnares the prior art, specifically the '406 Publication." Anderson Rebuttal Rep. § 313 (citing Anderson Opening Rep. § XIII). Mr. Anderson further states: "as explained in Section XVI.C. of my Opening Report, to the extent the claims of the '156 Patent are expanded under the doctrine of equivalents to include the Cipla ANDA Product, each limitation of the '156 Patent also reads on at least the third embodiment of the '406 Publication." Anderson Rebuttal Rep. § 314 (citing Anderson Opening Rep. § XVI.C). I disagree with Mr. Anderson.

256. As I explained in my Rebuttal Report in further detail and above and below, Mr. Anderson fails to demonstrate that Cipla's ANDA Product "practices the invention" of the '406 Publication, including what Mr. Anderson refers to as the "third embodiment." I have reviewed the documents that Mr. Anderson cites as the basis for that assertion (*see* Anderson Opening Rep. § XIII), and I disagree with his comparison between the '406 Publication and Cipla's ANDA Product. As I explain in my Rebuttal Report, the '406 Publication consists of a series of

two-dimensional images and text. Those disclosures do not support comparisons with the level of accuracy that Mr. Anderson purports to have conducted his analysis. That is especially true with respect to the '156 Patents, which require an evaluation of the relative positions of certain components (including, for example, the "actuator pawl" and "shoulder of a valve stem block") over time during operation of the inventions. *See* Lewis Rebuttal Rep. §§ IV.A, VI.B.2.b.

257. Nevertheless, even from the images in the '406 Publication, which I explain in my Rebuttal Report, it is apparent that Cipla's ANDA Product contains additional features recited by the Asserted Claims that the '406 Publication does not disclose. Among other deficiencies, the '406 Publication fails to does not describe in detail the locations of the components of the dose counters that it discloses, including the ones mentioned above, and does not describe in detail how those locations change over time during operation of those devices. Thus, the POSA could not determine from the '406 Publication the locations of the dose counter components when, for example, a given embodiment reaches the canister fire configuration (i.e., when the medicament canister fires medicament). Accordingly, as I opined in my Rebuttal Report, Mr. Anderson fails to demonstrate that the '406 Publication (including what Mr. Anderson what Mr. Anderson refers to as the "third embodiment") anticipates or render obvious the Asserted Claims of the '156 Patent. Certain components disclosed in the '406 Publication and Cipla's ANDA Product also appear to have obvious differences in their size, shape, and orientation, including with respect to the shape of what Cipla refers to as an "indexer" and the orientation of what Cipla refers to as a "leaf spring." *Compare, e.g.*, '406 Publication, Figs. 21, 26 *with* Cipla Samples; CIPLA-BDI_0156579 (Design Drawing). These differences, combined with the lack of information the '406 Publication, would compel the POSA to conclude that Cipla's ANDA Product did not "practice the invention" of the '406 Publication. I therefore disagree with Mr.

Anderson and incorporate my prior analysis as though fully set forth herein. *See, e.g.*, Lewis Rebuttal Rep. §§ IV.A, VI.B.2.b; *supra* Section V.A.3.

C. Cipla's ANDA Product Infringes the '808 Patent

1. Claim 1

258. Asserted claim 1 of the '808 Patent reads as follows:

> A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information,
> a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

'808 Patent, claim 1.

259. As I explained in my Opening Report, Cipla's ANDA Product literally infringes Asserted Claims 1, 27, and 28 of the '808 Patent. Mr. Anderson argues that Cipla's ANDA Product does not meet two limitations of Asserted Claim 1 of the '808 Patent, which he terms Limitation 1B ("a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input") and Limitation 1C ("wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements."). Mr. Anderson is incorrect, for the reasons I explain in detail below.

a. Cipla's ANDA Product Has "A Drive System Arranged to Move the Counter Display Incrementally in a First Direction from a First Station to a Second Station in Response to Actuation Input" (Limitation 1B)

260. I understand that the parties have agreed the term "first direction" should be construed to mean "a single direction at a time." I have applied this construction in the course of rendering my opinions.

261. I also understand Teva and Defendants disagree regarding the appropriate construction of the terms "first station" and "second station" and that the Court has not yet resolved their dispute. The competing constructions are reflected below.

Term	**Teva's Construction**	**Defendants' Construction**
"first station" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a first region"	"first structure on which the counter is located"
"second station" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a second region"	"second structure, separate from the first structure, to which the counter display is moved"

262. I do not offer any opinion regarding which of the proposed constructions is correct. However, it is my opinion that Cipla's ANDA Product satisfies Limitation 1B under either construction of the term "actuation member." I explain this opinion in more detail below.

1) Literal Infringement

263. As I explained in my Opening Report, ¶¶ 377-94, Cipla's ANDA Product a "drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input" where "first station" and "second station" mean "a first region" and "a second region," respectively. Mr. Anderson suggests that "the rotational movement of the tens cone and/or the units display ring does not reflect movement from a first region to a second region" and that I am "seemingly analyzing the movement of the units display ring and/or tens cone from the perspective of the individual digits displayed on those components." I disagree with Mr. Anderson's opinion, which appears to be based on a

misunderstanding of Asserted Claim 1 and Teva's construction rather than a disagreement about how Cipla's ANDA Product operates.

264. Without basis, Mr. Anderson assumes that a "drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input" must cause the counter display in Cipla's ANDA Product to translate along a horizontal axis like "the wheel on a car or bicycle in motion." Anderson Rebuttal Rep. ¶ 327. He likens this to the movement of a tape from one spool to another.

265. Nothing in Asserted Claim 1 or Teva's construction requires a particular kind of movement, as Mr. Anderson's opinion assumes. Rather, Asserted Claim 1 requires that the drive system "move the counter display incrementally" "in a single direction at a time" "from a first station to a second station." Nothing in that language requires linear movement rather than rotational movement. Upon actuation, the *entire* units teeth ring of Cipla's ANDA Product (not just a single digit on that units teeth ring) rotates (i.e., moves) in a single direction (counterclockwise). The tens cone remains still except once every ten actuations, when the *entire* tens cone also rotates (i.e., moves) in a single direction (clockwise).

266. Mr. Anderson also suggests that my opinion fails to give sufficient meaning for Asserted Claim 1's requirement that the counter display move incrementally from a first "region" to a second "region" (under Teva's construction). Anderson Rebuttal Rep. ¶¶ 326-30. He assumes that such movement can only occur if the entire counter display is transferred from point A to point B, in the same manner in which tape can unspool from one shaft and spool onto another. Again, nothing in Asserted Claim 1 or Teva's construction requires this kind of movement. Instead, a station is merely a "region" of the dose counter. As I explained in my opening report, "in Cipla's ANDA Product the first position corresponds to the region(s) of the

dose counter that are occupied by the current ones and/or tens digits; the second position corresponds to the region(s) of the dose counter that encompass the ones and/or tens digits after they increment." Lewis Opening Rep. ¶ 384.

2) Doctrine of Equivalents

267. Under the doctrine of equivalents, Cipla's ANDA Product also satisfies the limitation "drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input" where "first station" and "second station" are understood to mean "a first structure on which the counter is located" and a "second structure, separate from the first structure, to which the counter display is moved."

268. Mr. Anderson disagrees—he states that "[r]egardless of what Dr. Lewis contends constitutes the 'counter display' in Cipla's ANDA Product, no portion of that component (or components) would move from a first structure on which the counter is located to a second structure, separate from the first structure, to which the counter display is moved." Anderson Rebuttal Rep. ¶ 333. That statement appears to reflect Mr. Anderson's belief that Cipla's ANDA Product does not literally satisfy this limitation under Defendants' construction. That opinion misses the point—it is my opinion that Cipla's ANDA Product meets this limitation because it possesses a structure that is equivalent to the recited one (under Defendants' construction).

269. **Insubstantial Differences Test.** I explained in my Opening Report that, in the event Cipla's ANDA Product does not literally satisfy Limitation 1B under Defendants' construction, it possesses features that are insubstantially different from those recited in Limitation 1B. Lewis Opening Rep. ¶ 391. Mr. Anderson faults me for failing to identify anything in Cipla's ANDA Product that is equivalent to the first and second station structures. Anderson Rebuttal Rep. ¶ 334. Mr. Anderson is incorrect. As my opinion reflects, movement of the counter display from its position before incrementing to its position after incrementing (i.e.,

movement from a first position to a second position) is insubstantially different from movement of a counter display from a first structure to a second structure. Lewis Opening Rep. ¶ 391. Mr. Anderson's insistence that Cipla's ANDA Product cannot infringe if the counter display does not move from one structure to another structure again appears to focus on whether Cipla's ANDA Product literally infringes the claims, rather than infringing under the doctrine of equivalents.

270. **Function-Way-Result Test.** I also explained that Cipla's ANDA Product meets Limitation 1B under the doctrine of equivalents because its counter display performs the same function in the same way to achieve the same result as a counter display that moves incrementally from a first structure to a second structure, as Defendants' construction requires. Lewis Opening Rep. ¶ 392.

271. Mr. Anderson does not identify any particular flaw in my function-way-result analysis except to suggest that my "function" ("facilitating the counter display's informing the patient of the number of doses remaining") and "result" (facilitating the counter display's displaying the number of doses remaining") are too similar, and amount to "nothing more than assertion that the components of the ANDA Product collectively display the number of doses remaining. Anderson Rebuttal Rep. ¶ 335. I fail to understand Mr. Anderson's criticism, since he has not identified a different function or result that he views as more appropriate. As my Opening Report made clear, it is my opinion that the rotation of the units teeth ring and/or the tens cone from one position to another upon actuation performs substantially the same function (facilitating the counter display's informing the patient of the number of doses remaining) in substantially the same way (providing a starting and ending point for the counter display's movement) to achieve the same result (facilitating display of the number of doses remaining) as a dose counter that moves from one structure to another, like the tape in the embodiment

described in the '808 Patent. Mr. Anderson's argument that the "'way' must include at least some reference to the structural claim language under Defendants' proposed construction" again seems to reflect a literal infringement analysis rather than a doctrine of equivalents one. For clarity, it is my opinion that the counter display of Cipla's ANDA Product moves in a manner that is *equivalent* to moving from one structure to another. Mr. Anderson has offered no explanation of why this is not the case that does not depend on the literal absence of a feature.

b. Cipla's ANDA Product Has a "Regulator" "Arranged to Act Upon the Counter Display at the First Station to Regulate Motion of the Counter Display at the First Station to Incremental Movements" (Limitation 1C)

272. I have been informed that the parties have agreed that the term "regulator" should be construed to mean "a structure of the dose counter that modulates motion of the counter display"; and that the term "regulate motion of the counter display" should be construed to mean "modulate motion of the counter display." I have applied those constructions in rendering my opinion.

273. As I explained in my Opening Report, the leaf spring of Cipla's ANDA Product is the claimed regulator. Lewis Opening Rep. ¶ 398. I therefore disagree with Mr. Anderson that I have not identified any component of Cipla's ANDA Product that meets the parties' definition of a regulator. To the contrary, the leaf spring in Cipla's ANDA Product "modulates motion of the counter display" in that it applies (1) a resistance force opposite to the direction of the motion of the counter display before it counts and (2) a restoring force in the direction of the motion of the counter display after it counts." Lewis Opening Rep. ¶ 400.

274. Mr. Anderson asserts that, when the lid of Cipla's ANDA Product is removed, the leaf spring "can freely rotate within the units display ring." Anderson Rebuttal Rep. ¶ 338. Whether or not the leaf spring can rotate within the units teeth ring has nothing to do with

whether the leaf spring "modulates motion of the counter display." The leaf spring plainly does so, since it provides a resistive force against downward movement of the canister (which resists engaging, and therefore incrementing the dose counter), and then provides a restorative force in the opposite direction, which causes the dose counter components to complete the count. Lewis Opening Rep. ¶¶ 396-402. The leaf spring is directly in contact with both the units display ring (beneath the leaf spring) and the units teeth ring (above the spring), and thus acts on both these components in the course of applying force. *See* Lewis Opening Rep. ¶¶ 397-99 and Exhibit C; *see also* CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

275. Without the leaf spring, it would be easier to move the canister downward and thus easier to increment the dose counter. The leaf spring resists movement of the canister and therefore resists movement of the dose counter up until the point at which the dose counter is committed to counting. After that point, the leaf spring applies a restoring force pushing the canister upwards and ensuring that the counter completes its count and increments to the next full digit. Mr. Anderson is simply incorrect that the leaf spring "does not act upon any component of the 'counter display,'" Anderson Rebuttal Rep. ¶¶ 338, 343—to the contrary, it is situated directly between the units display ring and the units teeth ring. It acts on the units display ring by pushing against the units display ring—the fact that the units display ring is held stationary and cannot move downwards means that this action manifests in an upward force, that resists the downward movement of the canister.

276. Mr. Anderson takes issue with a statement in paragraph 398 of my Opening Report, in which I state that "as the patient presses down on the medicament canister, the leaf

spring applies a resistance force against the medicament canister in the opposite direction of its downward motion and, consequently in the opposite direction of the units display ring's and tens cone's motion." Lewis Opening Rep. ¶ 398. He "disagree[s] with the second half of this statement, because he asserts that the units display ring and/or tens cone rotate rather than moving in the same direction of the medicament canister. Anderson Rebuttal Rep. ¶ 339. He similarly disagrees that the leaf spring's restorative force is "in the direction of the motion of the counter display." Anderson Rebuttal Rep. ¶ 342. Mr. Anderson misunderstands my opinion—I do not suggest that the units display ring and tens cone move downwards with the canister, merely that "downward" is the direction of movement of the canister that first causes movement of the units display ring and tens cone. Likewise, the leaf spring's restorative force causes movement of the canister and dose counter components in a direction that facilitates, rather than resists movement of the units display ring and tens cone.

277. I also do not understand the import of Mr. Anderson's argument in paragraph 340. He asserts that "the small amount of rotation caused by the indexer pressing down on the units teeth ring does not, alone, cause the dose counter to incrementally record a count. Rather, the count occurs when the indexer and units display ring move upward and the teeth of the units display ring interact with the teeth of the lid." This additional detail does not change the role of the leaf spring as a regulator in the dose counter's operation. The spring resists the downward movement of the canister that is necessary to engage the dose counter and trigger a count, and then applies a "restorative" force that contributes to the upward motion of the teeth of the units display ring Mr. Anderson describes, which causes the dose counter to complete its counting process. My Opening Report nowhere suggests that the restorative force is applied in the same direction as the resistant force—to the contrary, it clearly portrays the restorative force as the

opposite of a resistant force. I had not anticipated Mr. Anderson's misunderstanding given the clear language I used, but to avoid any doubt—it is my opinion that the leaf spring first applies a resistant force (one that resists downward motion of the canister and the dose counter components situated above the leaf spring) and then a restorative force (one that encourages upward movement of the canister and the dose counter components situated above the leaf spring).

278. At the time that I served my Opening Report, Cipla's only disclosed non-infringement argument regarding this limitation related to the term "first station." *See* Lewis Opening Rep. ¶ 402. To the extent that Mr. Anderson is permitted to testify as to the new non-infringement theories set forth in his Rebuttal Report, in my opinion, Cipla's ANDA Product satisfies this limitation under the doctrine of equivalents.

279. The '808 Patent describes that the regulator modulates movement of the counter display, by applying (1) a resistance force opposite to the direction of the motion of the counter display before it counts and (2) a restoring force in the direction of the motion of the counter display after it counts, to help prevent the dose counter from counting a second time. *See, e.g.*, '808 Patent, 2:44-4:50, 17:62-20:11, Figs. 15-20. In other words, the regulator exhibits classic, spring-like behavior.

280. 420. The POSA would further understand that, in certain embodiments, the '808 Patent states that the dose counter comprises a display tape and that, in some of those embodiments, the regulator could comprise "a wavelike engagement surface with concavities which engage against control elements in the form of protrusions on resilient forks of a split pin." '808 Patent, 4:39-50. However, given the breadth of the '808 Patent's disclosures regarding the regulator, *see, e.g.*, '808 Patent, 2:44-4:50, 17:62-20:11, Figs. 15-20, the POSA would

understand that the design of the regulator would depend on the specific implementation of the counter display. Thus, the POSA would understand that to the extent that the '808 Patent describes the regulator as having a wavelike engagement surface, that was not an essential aspect of the inventions.

281. In my opinion, to the extent that any of Cipla's assertions are deemed correct, there are no substantial differences between Cipla's leaf spring and the claimed regulator. Both apply (1) a resistance force opposite to the direction of the motion of the counter display before it counts and (2) a restoring force in the direction of the motion of the counter display after it counts. Although Cipla's leaf spring is not identical to certain examples of regulators in the patent, the differences between Cipla's leaf spring and those examples are insubstantial because they do not relate to an essential aspect of the inventions.

282. Alternatively, in my opinion, Cipla's leaf spring and the claimed regulator perform substantially the same function in substantially the same way to obtain the same result. Both perform the function of modulating movement of the counter display, by way of applying (1) a resistance force opposite to the direction of the motion of the counter display before it counts and (2) a restoring force in the direction of the motion of the counter display after it counts, to obtain the result of result of helping prevent the dose counter from counting a second time. I address Cipla's ensnarement arguments below. *See infra* Section V.C.4.

2. Claim 27

283. Asserted Claim 27 recites, "The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display." As I explained in my Opening Report, Cipla's ANDA Product meets every limitation of Asserted Claim 27. Lewis Opening Rep. ¶¶ 403-07.

284. Mr. Anderson disagrees with me, because he asserts that the leaf spring applies no

force "against movement of the counter display" because the leaf spring can rotate freely within the units display ring. Anderson Rebuttal Rep. ¶ 346. He takes no issue with the accuracy of my measurement of the force of the leaf spring in my Opening Report, but rather claims that the measured force is applied to the canister by virtue of the units teeth ring, rather than "on" the units display ring or another part of the counter display.

285. Mr. Anderson misreads Asserted Claim 27. Nothing in Asserted Claim 27 requires that the regulator apply a rotational force against movement of the counter display, merely that it provides a "*resistance force* . . . against movement of the counter display." By pressing downward on the stationary units display ring (a part of the counter display), the leaf spring applies an upward force on the units teeth ring and canister of greater than 0.1 N, and that force resists movement of the counter display.

3. Claim 28

286. Asserted Claim 28 depends from Asserted Claim 27 and recites, "The dose counter as claimed in claim 27 in which the resistance force is greater than 0.3 N." As I explained in my Opening Report, Cipla's ANDA Product meets every limitation of Asserted Claim 28. Lewis Opening Rep. ¶¶ 408-11.

287. Mr. Anderson disagrees with me, because he asserts that the leaf spring applies no force "against movement of the counter display" because the leaf spring can rotate freely within the units display ring. Anderson Rebuttal Rep. ¶ 347. He takes no issue with the accuracy of my measurement of the force of the leaf spring in my Opening Report, but rather claims that the measured force is applied to the canister by virtue of the units teeth ring, rather than "on" the units display ring or another part of the counter display.

288. Mr. Anderson misreads Asserted Claim 28. Nothing in Asserted Claim 27 requires that the regulator apply a rotational force against movement of the counter display,

merely that it provides a "*resistance force* . . . against movement of the counter display." By pressing downward on the stationary units display ring (a part of the counter display), the leaf spring applies an upward force on the units teeth ring and canister of greater than 0.3N, and that force resists movement of the counter display.

4. Teva's Equivalents Theories Do Not Ensnare the Prior Art

289. In his Rebuttal Report, Mr. Anderson refers back to the opinions in his Opening Report and states that "to the extent that Dr. Lewis contends that the Cipla ANDA Product meets any claim of the '808 Patent under the doctrine of equivalents, such expansion of the claims improperly ensnares the prior art, specifically 'the '406 Publication'." Anderson Rebuttal Rep. ¶ 348 (citing Anderson Opening Rep. § XIII). Mr. Anderson further states: "as explained in Section XVII of my Opening Report, to the extent the claims of the '808 Patent are expanded under the doctrine of equivalents to include the Cipla ANDA Product, each limitation of '156 Patent [sic] also reads on at least the third embodiment of the '406 Publication." Anderson Rebuttal Rep. ¶ 349 (citing Anderson Opening Rep. § XVII). I disagree with Mr. Anderson.

290. As I explained in my Rebuttal Report and above and below in further detail, Mr. Anderson fails to demonstrate that Cipla's ANDA Product "practices the invention" of the '406 Publication, including what Mr. Anderson refers to as the "third embodiment." I have reviewed the documents that Mr. Anderson cites as the basis for that assertion (*see* Anderson Opening Rep. § XIII), and I disagree with his comparison between the '406 Publication and Cipla's ANDA Product. As I explain in my Rebuttal Report, the '406 Publication consists of a series of two-dimensional images and text. Those disclosures do not support comparisons with the level of accuracy that Mr. Anderson purports to have conducted his analysis. That is especially true with respect to the '808 Patent, which requires an evaluation of the forces and interactions between multiple components (including, for example, the "regulator" and "counter display").

See Lewis Rebuttal Rep. §§ IV.A, VI.C.2.c.

291. Nevertheless, even from the images in the '406 Publication, which I explain in my Rebuttal Report, it is apparent that Cipla's ANDA Product contains additional features recited by the Asserted Claims that the '406 Publication does not disclose. Among other deficiencies, the '406 Publication nowhere discloses the above-mentioned regulator or the manner in which the components in which Mr. Anderson asserts to correspond to the regulator interact. Thus, as I opined in my Rebuttal Report, Mr. Anderson fails to demonstrate that the '406 Publication (including what Mr. Anderson refers to as the "third embodiment") anticipates or render obvious the Asserted Claims of the '808 Patent. Certain components disclosed in the '406 Publication and Cipla's ANDA Product also appear to have obvious differences in their size, shape, and orientation, including with respect to the shape of what Cipla refers to as an "indexer" and the orientation of what Cipla refers to as a "leaf spring." *Compare, e.g.*, '406 Publication, Figs. 21, 26 *with* Cipla Samples; CIPLA-BDI_0156579 (Design Drawing). These differences, combined with the lack of information the '406 Publication, would compel the POSA to conclude that Cipla's ANDA Product did not "practice the invention" of the '406 Publication. I therefore disagree with Mr. Anderson and incorporate my prior analysis as though fully set forth herein. *See* Lewis Rebuttal Rep. §§ IV.A, VI.C.2.c.

VI. The Claimed Inventions Exhibit Numerous Objective Indicia of Non-Obviousness

292. In my opening report, I opined that numerous objective indicia supported the non-obviousness of the Asserted Claims. See Lewis Opening Rep. § IX. For this report, I have been asked to respond to the Opening Report of Mr. Anderson, dated April 29, 2022, and the Rebuttal Report of Mr. Anderson, dated June 14, 2022, in which he provides contrary opinions regarding these objective indicia. As explained in my Opening Report and below, I disagree with each of Mr. Anderson's criticisms. If Mr. Anderson is permitted to expand or further supplement his

analysis, I reserve the right to offer additional opinions that address any new assertions.

A. Mr. Anderson's Opinions Regarding Objective Indicia Are Incorrect.

1. Long-Felt, Unmet Needs

293. Mr. Anderson opines that the inventions recited in the Asserted Claims did not satisfy the long-felt, unmet needs I identified in my opinion report because (1) prior-art devices satisfied these needs; (2) these needs did not exist or had been satisfied; and (3) Qvar® HFA with dose counter and ProAir® HFA with dose counter did not satisfy these needs. *See* Anderson Rebuttal Rep. on Secondary Considerations § XI. Mr. Anderson is incorrect for the reasons set out below and in my Opening Report. I incorporate by reference my prior opinions as though fully set forth herein. *See* Lewis Opening Rep. § IX

a. Prior Art Devices Did Not Satisfy Those Needs.

294. Mr. Anderson states that "most" of the long-felt needs set out above simply "relate to the desire for a dose counter on an inhaler generally." Anderson Rebuttal Rep. on Secondary Considerations ¶ 25. Mr. Anderson also states that "[d]ose counters, and dose counters on inhalers were well-known and commercially available by 2009," and these devices satisfied the needs set out above. Anderson Rebuttal Rep. on Secondary Considerations ¶ 25. I disagree with Mr. Anderson on both issues.

295. First, as set forth in my Opening Report and below, the needs satisfied by the Asserted Patents do not "relate to the desire for a dose counter on an inhaler generally." Instead, they satisfied multiple, *specific*, long-felt needs in the field of pulmonary medicine, including, the needs for inhalers with dose counters that had sufficient functionality, accuracy (including with respect to under- and over-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors). *See* Lewis Opening Rep. § IX.

296. Second, as set forth in my Opening Report and below, the dose counters that were commercially available as of the priority date, including the dose counters purportedly disclosed by the '406 Publication or included in Ventolin® HFA, Flovent® HFA, Advair® Diskus, and Serevent® Diskus, did not satisfy the need for devices with the properties of the claimed inventions. *See* Lewis Opening Rep. § IX.

1) The '406 Publication

297. Mr. Anderson asserts that the '406 Publication discloses and inhaler with a dose counter that was "developed years before the asserted patents" and which "satisfied any need for an inhaler with a dose counter having sufficient functionality, accuracy, reliability, maintainability, robustness, manufacturability, minimal impact on device performance and human factors." Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 26-28; Anderson Opening Rep. ¶¶ 472-73 (similar). I disagree.

298. As an initial matter, Mr. Anderson has not demonstrated that the '406 Publication "discloses the dose counter used in the Cipla and Aurobindo inhalers" and the "dose counter used in Dulera®." Anderson Rebuttal Rep. on Secondary Considerations ¶ 26. As I explain at length in my Rebuttal Report and above, the '406 Publication does not disclose the dose counter (or inhaler/dose counter combination) that is used in Cipla's and Aurobindo's ANDA Products. Nor does the '406 Publication anticipate or render obvious the Asserted Claims. *See* Lewis Rebuttal Rep. §§ IV.A, VI; *supra* Sections V.A.3, V.B.6, V.C.4. I incorporate by reference those opinions as though fully set forth herein.

299. Mr. Anderson is further incorrect that the '406 Publication's disclosures satisfied the needs for an inhaler with a dose counter "sufficient functionality, accuracy, reliability, maintainability, robustness, manufacturability, minimal impact on device performance and human factors." Notably, the '406 Publication provides no evidence that any of its disclosures

satisfy any of these needs, much less all of them. *See, e.g.*, '406 Publication, ¶ [0006]. This is particularly remarkable in light of the fact that the '406 Publication acknowledges that robustness, reliability, manufacturability, accuracy, precision, and unwanted actuation are significant features for a dose counter. *See, e.g.*, '406 Publication, ¶ [0006].

300. Mr. Anderson further offers a number of opinions based on the assumption that the '406 Publication discloses a dose counter used in certain 3M products, including by opining that (1) FDA's approval of a 3M dose counter shows that the '406 Publication's "dose counter is safe and effective"; (2) the '406 Publication's dose counter has a "lifespan" that crosses "multiple products"; (3) "Defendants' testing also demonstrates that the . . . ['406 Publication's] dose counter is safe, effective, reliable, and meets patient needs"; and (4) the '406 Publication's dose counter "addressed any needs identified by FDA's industry guidance." Anderson Rebuttal Rep. on Secondary Considerations ¶ 28. Again, I disagree with Mr. Anderson.

301. Once more, Mr. Anderson fails to show that the '406 Publication actually discloses a dose counter that is used in the products he identifies (e.g., Dulera®). And even if Mr. Anderson's position were accurate, whether the '406 Publication discloses a dose counter that has received FDA approval does not mean that the device satisfied the needs that I identified in my report —*i.e.*, superior functionality, accuracy (including with respect to under- and over-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors).

302. To the contrary, none of the devices that Mr. Anderson relies on satisfied the needs, and combination of needs, by the claimed inventions.

2) Ventolin® HFA, Flovent® HFA, Advair® Diskus, and Serevent® Diskus

303. In addition, Mr. Anderson states that as of 2009, there were "numerous inhalers" with dose counters, including, "the Ventolin HFA, Flovent HFA, Advair Diskus, and Serevent Diskus." Anderson Rebuttal Rep. on Secondary Considerations ¶ 29; *see also* Anderson Opening Rep. ¶¶472-73 ("[N]umerous dose counters were marketed prior to May 2009."). According to Mr. Anderson, those inhalers "all had dose counters that provided the functionality, accuracy, reliability, maintainability, robustness, manufacturability, minimal impact on device performance and human factors." Anderson Rebuttal Rep. on Secondary Considerations ¶ 29. Mr. Anderson is incorrect.

304. As set forth in my Opening Report, the Advair® HFA, Ventolin® HFA, and Flovent® HFA include counting mechanisms that are fixed near the valve of the canister. *See* Lewis Opening Rep. ¶¶ 469-70. Attaching the dose counter to medicament canister significantly limited their compatibility with existing medicament canisters and canister housings.

305. Additionally, the Advair® Diskus and Serevent® Diskus inhalers presented further problems. *See* Lewis Opening Rep. ¶ 470. As I explain in my Opening Report, solutions suitable for breath-actuated dry powder inhalers (such as the Diskus devices) are generally inappropriate for metered dose inhalers because, for example, they did not need to account for variations in stroke length, which posed a significant problem for metered dose inhalers. In breath-actuated dry powder inhalers, the patients typically provide some additional action, which further assists in causing the mechanism to count. *See, e.g.*, '289 Patent, 1:27-2:20.

306. Mr. Anderson asserts that "human factors" such as "aesthetics or ergonomic value" are "not claimed (or meaningfully described) in any of the asserted patents." Anderson Rebuttal Rep. on Secondary Considerations ¶ 30; *see* Anderson Opening Rep. ¶ 477. In my opinion, Mr. Anderson's assertion is based on an improperly limited analysis of the Asserted

Claims. I have been informed that nexus does not require that a claim expressly state the advantages of a patented invention. In this case, although the claims do not mention "aesthetics" or "ergonomics" in as many words, the combination of mechanical elements recited in each of the Asserted Claims results in the aesthetic and ergonomic advantages.

307. Mr. Anderson is also incorrect that, just because FDA had approved Ventolin® HFA, Flovent® HFA, Advair® Diskus, and Serevent® Diskus, no needs existed. Anderson Rebuttal Rep. on Secondary Considerations ¶ 30. Mr. Anderson assumes that FDA's guidances conclusively establish the needs of the field. In my experience, however, while FDA's guidances set forth minimum requirements, physicians and patients often face additional needs not expressly addressed in those guidances. I understand that Dr. Panettieri has offered additional opinions to the same effect from the perspective of a physician, and his opinions comport with my own. *See* Panettieri Reply Rep. § VI.A.1.b. Indeed, as I explain above, these devices failed to meet combinations of two or more of the claimed properties of the Asserted Claims, including, superior functionality, accuracy (including with respect to under- and over-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors).

308. Mr. Anderson offers a variety of arguments responding to my opinions that dose indicators failed to satisfy the needs dose counters and dose indicators, including that (1) FDA Guidance "explicitly references dose indicators as an acceptable option"; (2) "Conn[e]r 2013 makes clear that only certain types of dose indicators are considered to be less precise," and (3) "Conn[e]r 2013 post-dates the Asserted Patents and therefore does not reflect any long felt, unmet need at the time of the invention." Anderson Rebuttal Rep. on Secondary Considerations

¶ 31. Mr. Anderson further states "there were numerous inhalers on the market at the time of the priority date of the asserted patents and at the time of Conn[e]r 2013, and none of these solely used color coded or indicator symbols." Anderson Rebuttal Rep. on Secondary Considerations ¶ 31. I disagree with each of these arguments.

309. As explained above, the FDA Guidance sets out a minimum baseline in terms of what properties every inhalation device on the market should include. The literature that I cite in my Opening Report confirms that the FDA Guidance set only a minimum baseline. Although Mr. Anderson criticizes my interpretation of Conner 2013, that reference supports my opinions. Among other things, Conner 2013 analyzes the shortcomings of dose indicating devices, including those on the market as of the priority date, *see* Lewis Opening Rep. ¶ 466, that use color coded display or indicator symbols, s*ee* Conner 2013, TEVADOC-00000312, at -315 ("Dose indicators that rely solely on color coded display or indicator symbol . . . are less precise than dose counters that use a numeric display . . . ."). As Dr. Panettieri explains in his Opening Report, these types of devices were not effective for numerous patients. *See* Panettieri Reply Rep. § VI.A.1.b. Mr. Anderson's assertion that Connor 2013 does not accurately reflect the state of the art is belied by both my and Dr. Panettieri's experience as well as the published literature.

310. Finally, Mr. Anderson asserts that many of the references set forth in my Opening Report do "track each dose dispensed (and therefore each dose remaining)," including the Sapphire and Senetics patents I identify. Anderson Rebuttal Rep. on Secondary Considerations ¶ 32. I disagree. Neither of the dose counters that Mr. Anderson cites clearly disclose that. Sapphire '827 discloses a "level indicator" that "slidably extends through a longitudinal slot in the housing" in order to indicate the "remaining amount of medicament." *See* Sapphire '827, 3:35-37, Abstract. And Senetics '355 states only that the indicator wheel "may be in the form of

a sequence of numbers," without further explanation Anderson Rebuttal Rep. on Secondary Considerations ¶ 32 (quoting Senetics '355, 4:45-50). I address both devices in my Opening Report and incorporate those opinions as though fully set forth herein.

311. In opining that the Sapphire and Senetics devices, Mr. Anderson focuses on the parties' claim construction dispute regarding the term "counter display arranged to indicate dosage information." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Relevant for purposes of my opinions here, as I explain below in greater detail, each of the Asserted Claims recites a "dose counter." Regardless of the claim construction issues raised by Mr. Anderson, the dose indicating devices disclosed in Sapphire '827 and Senetics '355 fall well short of that. As such, I disagree with Mr. Anderson.

b. The Identified Needs Were Not Addressed as of the Priority Date

312. In addition to his discussion of the devices addressed above, Mr. Anderson asserts that the other references set out in my Opening Report fail to support any "opinions that the asserted patents solved . . . alleged needs" in the industry. Anderson Rebuttal Rep. on Secondary Considerations ¶ 33. I disagree with each of Mr. Anderson's criticisms.

1) FDA Guidance 2003

313. In my Opening Report, I relied on FDA's Guidance as evidence of long-felt, unmet need. Mr. Anderson criticizes my analysis of the FDA Guidance for several reasons, none of which undermine my analysis.

314. Mr. Anderson opines that the FDA Guidance was published "six years before the alleged priority date of the asserted patents" and therefore does not accurately reflect the state of the art. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 34; Anderson Opening Rep. ¶ 472. Mr. Anderson is incorrect. As I explain throughout in my Opening Report, the needs

identified by the FDA Guidance persisted through the priority date and beyond. Indeed, in my Opening Report, I specifically address multiple prior art references published in the intervening years following the FDA Guidance's publication. *See, e.g.*, Lewis Opening Rep. §§ IX.A.1-2, B. Moreover, as set forth above, I did describe several prior art references and disclosures that were developed between 2003 and 2009. *See, e.g.*, Lewis Opening Rep. § IX. Further, the prior art devices that Mr. Anderson relies on in Section XI.A of his Rebuttal Report on Secondary Considerations do not meet the multiple, specific, long-felt needs set forth in my Opening Report. *See supra* § VI.A.1.a. That these and other products used counting mechanisms does not prove that those mechanisms were precise, reliable, and/or accurate.

315. Additionally, Mr. Anderson opines that my reliance on the FDA Guidance as evidence of long-felt unmet need contradicts my opinions regarding dose indicators because the FDA Guidance approves their use. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 36. No contradiction exists. As I explain above, the FDA Guidance provides a baseline for what properties every inhalation device on the market should include. That the FDA Guidance recognizes certain needs, however, does not mean that that other needs do not exist.

316. Mr. Anderson also states that the needs recited in the FDA Guidance and recounted in my Opening Report are "generic." Anderson Rebuttal Rep. on Secondary Considerations ¶ 37. I disagree. The needs set forth in FDA's Guidance speak for themselves, and the fact that FDA and others found it necessary to repeat them demonstrates both their significance and the non-obviousness of their solutions.

317. Mr. Anderson's analysis of Mr. Walsh's testimony repeats his mistaken view that just because FDA approved a particular product, that it necessarily satisfied any needs, including those reflecting in FDA's Guidance. On that point, Mr. Anderson states that "Teva's corporate

designee [Mr. Walsh] testified that by 2009 there were devices on the market that addressed any needs identified in the FDA guidance, but Teva's 'products, both Qvar® and ProAir®, . . . still had not addressed the need. Thus, by 2009, these needs were specific to Teva, not the industry at large." Anderson Rebuttal Rep. on Secondary Considerations ¶ 39 (citations omitted). Mr. Anderson's characterization of Mr. Walsh's testimony is inaccurate. That dose counters and other counting mechanisms were available on the market as of the priority date does not indicate that those products satisfied the 2003 FDA Guidance, let alone the multiple, specific, long-felt needs set forth in my Opening Report. *See* Lewis Opening Rep. § IX.

318. In passing, Mr. Anderson mentions the discontinuation of Qvar® HFA with dose counter. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 35. I do not understand what point Mr. Anderson is attempting to make, but it does not undermine my opinions. Teva discontinued that product for "business reasons" "unrelated to the well-established safety and effectiveness of the product." TEVAQVAR-00015375. In my experience, those kinds of business-related decisions are common and not evidence of any issues with the devices.

2) Ogren 1995, Broeders 2009, Sander 2006, Hess 2008, Holt 2005, Fink 2005, the '021 Publication, and Williams 1999

319. In addition to the FDA Guidance, in my Opening Report, I cited a number of references to support my opinions, including Ogren 1995, Sander 2006, Hess 2008, Holt 2005, Fink 2005, the '021 Publication, and Williams 1999. As with the FDA Guidance, Mr. Anderson's criticisms of that analysis fail to demonstrate any errors in it.

320. As an initial matter, Mr. Anderson opines that each of these references "merely identify[] the generic desirability of a dose counter." ¶ 40. Mr. Anderson is incorrect. As set forth in my Opening Report and below, each of these references identified multiple, *specific*, long-felt needs, with respect to accuracy and precision (FDA Guidance 2003; Holt 2005; Sander

2006; Ogren 1995; Fink 2005; Hess 2008; Broeders 2009); manufacturability and maintainability, especially in connection with mechanical or electronic complexity and cost ('021 Publication); robustness ('021 Publication), and other issues, including poor reliability, ergonomics, and compatibility (Hess 2008; Williams 1999). *See* Lewis Opening Rep. § IX.A.1. Mr. Anderson fails to show any error in that analysis.

321. Additionally, Mr. Anderson further opines that "these references cannot possibly take into account the state of the industry" at the time of the priority date because these references were written or published before the priority date. Anderson Rebuttal Rep. on Secondary Considerations ¶ 40; Anderson Opening Rep. ¶ 472 (similar). Again, I disagree. Based on my personal experiences working with companies developing inhalation aerosol devices, the needs identified in these references persisted as of the priority date. *See* Lewis Opening Rep. § IX. Mr. Anderson's contrary assertion is without basis.

322. Mr. Anderson also repeats his assertion that Ventolin® HFA, Flovent® HFA, Serevent® Diskus, Advair® Diskus, and Dulera® met the multiple, specific, long-felt, unmet needs set forth in my Opening Report. Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 40-41. As I discuss in more detail above, these devices did not satisfy the multiple, specific, long-felt, unmet needs that existed in the industry as of the priority date. *See supra* § VI.A.1.a. The same is true of the other devices that Mr. Anderson addresses, including the Doser™ and MD Turbo™. Anderson Rebuttal Rep. on Secondary Considerations ¶ 41. As I explain in my Opening Report, both devices suffered from multiple problems indicating the need for further development—including, because were extremely bulky suffered from poor compatibility and, in some cases, unreliability. *See* Lewis Opening Rep. ¶¶ 472-73.

323. Remarkably, Mr. Anderson asserts that "supports Defendants' position" because

it describes the devices mentioned in the paragraph above. Anderson Rebuttal Rep. on Secondary Considerations ¶ 41. He further criticizes me for purportedly ignored Hess 2008's citation to Seth 2006, he states, "evaluated a pMDI with an integrated dose counter." Anderson Rebuttal Rep. on Secondary Considerations ¶ 41. Mr. Anderson's logic is backwards. In my Opening Report, I explained in detail why Hess 2008 evidences the continuing existence of the needs mentioned in my report. *See, e.g.*, Lewis Opening Rep. ¶¶ 441, 449, 472-73. That Hess 2008 continued to reflect the needs I identified ***despite*** referring to these devices supports my opinions, not Defendants' position.

3) Pre-Dose Counter Tests

324. In addition to criticizing my analysis of the references that I cite in my Opening Report, Mr. Anderson states that "pre-dose counter tests" are not evidence of any long-felt, unmet needs and that the "needs identified are generic and would be solved by any dose counter." Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 42-43. He further states that this need does not "relate specifically to a need solved by the dose counters claimed in the asserted patents." Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 42-43. I disagree.

325. To begin with, Dr. Panettieri offers the opinion that in his experience as a treating physician in the field of pulmonary medicine, patients continued to use these "pre-dose counter tests" as of the priority date even after companies implemented counting mechanisms in their inhalers because these counting mechanisms were not sufficiently precise, accurate, reliable, or usable. *See* Panettieri Opening Rep. ¶¶ 45-63. That is consistent with my experience. As of the priority date, there were devices on the market that lacked sufficiently precision, accuracy, reliability, or usability. *See* Lewis Opening Rep. § IX. Thus, Mr. Anderson is incorrect that the continued use of "pre-dose counter tests" is not evidence of the needs I identified.

326. Moreover, the evidence belies Mr. Anderson's assertion that the continued use of

"pre-dose counter tests" reflected only generic needs. As set forth in my Opening Report, several devices and disclosures in the prior art did not meet the need for an accurate, precise dose counter, because they did not report to patients the precise number of doses remaining in their inhalers. *See* Lewis Opening Rep. § IX. Counting mechanisms in the prior art provided only a general indication of the number of doses remaining, for example, by displaying the number of doses in multiples of ten or by using colors. *See*, e.g., Stuart 2013, TEVADOC-00000531, at -531 ("[Dose indicators] often do not index every count and require some patient interpretation of the display . . . . [Dose indicators] are not considered by patients to be as accurate as dose counters."); Conner 2013, TEVADOC-00000312, at -315 ("Dose indicators that rely solely on a color coded display or indicator symbol . . . are less precise than dose counters that use a numeric display . . . ."); '289 Patent, 2:9-12. I therefore disagree.

4) Cleanability

327. Mr. Anderson's opinions regarding the long-felt, unmet need for inhalers with dose counters that were sufficiently cleanable repeats many of the errors in his analysis. Mr. Anderson asserts that there is no nexus between "cleanability" and the Asserted Claims. Anderson Rebuttal Rep. on Secondary Considerations ¶ 44; *see* Anderson Opening Rep. ¶ 477. Mr. Anderson also asserts that other devices in the prior art were "cleanable." *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 45. I disagree with both assertions.

328. With respect to his analysis of nexus, Mr. Anderson is incorrected for the reasons explained above. As before, Mr. Anderson appears to focus on the fact that the terms "maintainability" or "ability to be cleaned" or similar phrases do not appear in the Asserted Patents. In this case, however, inventions set forth in the Asserted Claims provide the unique combination of elements from which these advantages flow. Because the Asserted Claims describe the inventions in terms of their design, it is not surprising that the Asserted Claims do

not refer to these terms. It is those designs that solved the needs set forth above. *See supra* § VI.A.1.

329. Mr. Anderson asserts that, "[b]ased on how Plaintiffs interpret claims for infringement, Plaintiffs do not contend that the asserted claims require a separate dose counter chamber because one does not exist in Defendants' ANDA Products." Anderson Rebuttal Rep. on Secondary Considerations ¶ 44. Mr. Anderson is incorrect to the extent that he opines that cleanability relates solely to the existence of a "separate counter chamber," as Defendants propose the term should be construed. Maintainability (and ability to be cleaned) also flow from other claimed features of the inventions—*e.g.*, the location of the dose counter and other components with respect to other components in the inhalation device.

330. Mr. Anderson opines that the '406 Publication and a Bespak device satisfied the needs of the claimed inventions, including maintainability (and the ability to be cleaned). He also asserts that the '406 Publication "would be equally cleanable" to the claimed inventions embodied in Qvar® HFA with dose counter and ProAir® HFA with dose counter. Nowhere, however, does Mr. Anderson provide any support for his opinion. Moreover, neither the claims nor any part of the '406 Publication require any combinations of features that facilitates maintainability (and ability to be cleaned).

331. Moreover, with respect to the Bespak device, Mr. Anderson relies on a misinterpretation of Mr. Declan Walsh's testimony. Mr. Anderson states that Mr. Declan Walsh "testified that a known Bespak device that included a dose counter would have been washable," and that "[h]e further testified that it is a characteristic of the inhaler that determines whether it needs washing, not the dose counter itself." Anderson Rebuttal Rep. on Secondary Considerations ¶ 45. Mr. Anderson misinterprets the cited testimony. At his deposition, Mr.

Walsh was asked: "Was – is the Bespak *dose counter* cleanable?" Walsh Dep. Tr. 194:21-22. Mr. Walsh responded: "[S]o there is no dose counter that I am aware of where people are instructed to wash the *dose counter*. There are inhalers with drug products on the marke[t] and the *inhaler itself* requires washing occasionally to maintain its pharmaceutical performance. So is the Bespak dose counter cleanable? You could wash it. You could introduce it to water. Why would you do it? I don't know." Walsh Dep. Tr. 195:15-196:2 (emphases added). Nothing in that exchange supports Mr. Anderson's interpretation of it.

c. Qvar® HFA and ProAir® HFA Satisfied Multiple, Long-Felt Needs

332. In addition to opining that no long-felt, unmet needs existed, Mr. Anderson opines that Qvar® HFA with dose counter and ProAir® HFA with dose counter did not solve them. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 46. Mr. Anderson is incorrect for the reasons set forth in my Opening Report and below.

333. As an initial matter, Mr. Anderson repeats his assertion that several prior art dose counters addressed the alleged needs set forth in my Opening Report. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 47. However, as set forth above, the devices that Mr. Anderson relies on in Section XI.A of his Rebuttal Report on Secondary Considerations do not support his argument. *See supra* § VI.A.1.a. I incorporate those arguments by reference as though fully set forth herein.

1) "Counter Display Arranged to Indicate Dosage Information"

334. As noted above, Mr. Anderson's analysis of dose indicators appears to rely on a claim construction argument involving the parties' proposed constructions of the term "counter display arranged to indicate dosage information." *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 48. Mr. Anderson appears to opine that counting mechanisms, such as dose

indicators, fall within the scope of the Asserted Claims under Teva's proposed construction of the term to mean a "component of the dose counter that display information regarding the number of doses remaining." Anderson Rebuttal Rep. ¶ 48.

335. I have been informed that the parties have proposed different constructions for the term "counter display arranged to indicate dosage information." I have been informed that Teva proposed that the term should be construed according to its plain and ordinary meaning, in view of the claims, specification, and prosecution history, to mean "a component of the dose counter that display information regarding the dosage remaining." I have been informed that Defendants propose that the terms should be construed to mean "structure displaying the number of doses remaining." I have not been asked to provide an opinion which construction is correct, and I express no opinion on this issue.

336. Regardless, in my opinion, Mr. Anderson's focus on the parties' dispute over the term "counter display" is misplaced. While Mr. Anderson focuses on that term, he fails to grapple with the fact that the claimed inventions require "dose counters," not dose indicators. Accordingly, it is plain that the claimed inventions do not cover the types of dose indicating devices that Mr. Anderson asserts fall within the scope of the claims.

337. Additionally, Mr. Anderson asserts that "a lack of electrical circuity is not a requirement of any claim of the asserted patents," and that "the ergonomics and cleanability of the inhaler are . . . not required by any of the asserted claims." Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 49-50. Mr. Anderson therefore concludes that the "alleged satisfaction of long-felt needs lack the requisite nexus to the patent claims." Anderson Rebuttal Rep. on Secondary Considerations ¶ 50; *see* Anderson Opening Rep. ¶ 477.

338. Once again, Mr. Anderson's focus on whether the Asserted Claims recite their

advantages in express terms is misplaced. As evidenced by the Asserted Claims, each recites a combination of mechanical elements that supports these advantages. *See, e.g.*, '289 Patent, Claim 1 (reciting "operation by movement of the medicament canister"); '587 Patent, Claims 1, 12-13 (similar); '156 Patent, Claim 1 (reciting mechanical components such as "ratchet wheel," "actuator pawl," and "count pawl"); '808 Patent, Claim 1 ("regulating motion" of the counter display "in response to actuation input"). Mr. Anderson's focus on the phrase "lack of electrical circuitry" and similar phrases does not demonstrate a lack of nexus. I address Mr. Anderson's arguments regarding ergonomics above, and I incorporate that analysis as though fully set forth herein. *See supra* § VI.A.1.a.2.

2) Given 2012 and Chipps 2017

339. Mr. Anderson asserts that Given 2012 and Chipps 2017 fail to support the conclusion that Qvar® HFA with dose counter and ProAir® HFA with dose counter satisfied the long-felt, unmet needs set forth in my Opening Report. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 52; Anderson Opening Rep. ¶ 475. Mr. Anderson is incorrect.

340. As an initial matter, Mr. Anderson seeks to undermine these studies by stating that Teva funded them. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 52; Anderson Opening Rep. ¶ 475. That, however, does not undermine their reliability. In my experience, pharmaceutical companies, such as Teva, commonly fund studies using their products or proposed products, and the fact of that funding is not a reason to doubt their accuracy. Indeed, because pharmaceutical companies rely on those studies to evaluate their products and proposed products, it is in the investigators' interests to provide accurate feedback.

341. In any event, Mr. Anderson does not demonstrate any flaws in those studies' methodologies or their results. I have independently reviewed each of those studies, and I disagree with Mr. Anderson's criticisms.

342. In particular, Mr. Anderson states that "in the Given 2012 study, the only dose counter used was the ProAir HFA MDI, so this study could not conclude that the dose counter was more reliable or accurate than existing dose counters." Anderson Rebuttal Rep. on Secondary Considerations ¶ 52; Anderson Opening Rep. ¶ 475 (similar). Mr. Anderson also asserts that "the Chipps 2017 study concluded only that ProAir HFA with a dose counter had 'lower healthcare resource use including all-cause and respiratory-related and inpatient and ED visits, higher refill rates, and fewer exacerbations.'" Anderson Rebuttal Rep. on Secondary Considerations ¶ 52; Anderson Opening Rep. ¶ 475 (similar). According to Mr. Anderson, "[n]either of these studies concludes that the dose counter addressed some need in the industry that the prior art had not addressed at least because they fail to analyze the dose counters in existence prior to the priority date of the asserted patents." Anderson Rebuttal Rep. on Secondary Considerations ¶ 52; Anderson Opening Rep. ¶ 475 (similar).

343. I disagree with Mr. Anderson's interpretation of those studies. Contrary to his assertion, the fact that Given 2012 and Chipps 2017 did not perform a head-to-head comparison does not mean that they fail to demonstrate the successes of the inventions recited in the Asserted Claims in addressing the long-felt, unmet needs discussed in my analysis. To the contrary, those studies demonstrate that, unlike the other devices discussed in my Opening Report and above, the claimed inventions satisfied those needs where others failed. In addition, I disagree with Mr. Anderson's implication that "lower healthcare resource use including all-cause and respiratory-related and inpatient and ED visits, higher refill rates, and fewer exacerbations" is not an advantage. I therefore disagree with Mr. Anderson's conclusions.

3) Ms. Carr's Testimony

344. [redacted]

[redacted] As I explain below in greater detail, I disagree with Mr. Anderson's contrary analysis of that testimony. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 53-55.

345. As [redacted]

346. [redacted]

[redacted]

348. [redacted]

349. [redacted]

[redacted]

2. Failure of Others

350. In my Opening Report, I opined that others tried, but failed to develop inhalers with dose counters having the desirable properties of the inventions recited in the Asserted Claims. In response, Mr. Anderson opines that features such as "compactness, ergonomics, maintainability, cleanability, ease of manufacture, ease of assembly, and expense lack any nexus to the claims of the Asserted Patents." Anderson Rebuttal Rep. on Secondary Considerations ¶ 56; *see* Anderson Opening Rep. ¶ 477. He further opines that others did not fail to develop devices having those features. *See, e.g.*, Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 57-58. Mr. Anderson is incorrect.

351. As I explain above, Mr. Anderson's analysis of the Asserted Claims is overly limited. I have been informed that nexus does not require that a claim expressly describe the advantages of a patented invention. Here, each of the Asserted Claims recites a combination of mechanical elements that results in devices having the claimed features. Although the Asserted Claims do not mention the qualities that Mr. Anderson identifies in as many words, they nevertheless recite the elements that result in those qualities. I therefore disagree with Mr. Anderson. *See supra* §§ VI.A.1.a.2; VI.A.1.b.4; VI.A.1.c.1.

352. Relatedly, Mr. Anderson opines that "Teva's claims of secondary considerations are identical even though the claimed inventions are the four Asserted Patents are allegedly different, further showing that Teva has not demonstrated any nexus or connection between any actual Asserted Claim of an Asserted Patent and alleged secondary consideration." Anderson Opening Rep. ¶ 477. Mr. Anderson is incorrect. Again, as I explain above, each of the Asserted Claims recites a combination of elements that contributes to the desirable qualities of the inventions. *See supra* §§ VI.A.1.a.2; VI.A.1.b.4; VI.A.1.c.1. Mr. Anderson appears to assume

that the desirable qualities that I identify are binary qualities that exist or do not. That assumption is incorrect.

353. Regarding the failures of others themselves, Mr. Anderson's repeats his assertion that "others did not fail in making accurate, reliable, robust devices." Anderson Rebuttal Rep. on Secondary Considerations ¶ 57 (citing Anderson Rebuttal Rep. § XI.A). As I explain above, Mr. Anderson is incorrect. *See supra* § VI.A.1.a.

354. Mr. Anderson also appears to make a claim construction argument regarding the Newtec device based on Teva's proposed construction of "counter display." Anderson Rebuttal Rep. on Secondary Considerations ¶ 58. As I explain above, Mr. Anderson's claim construction analysis is misdirected. The Asserted Claims require dose counters, and the Newtec and other devices that Mr. Anderson identifies in connection with his claim construction argument fall well short of that, including for the reasons set forth in my Opening Report and above. As such, Mr. Anderson is incorrect for the reasons set forth above, and I incorporate that analysis as though fully set forth herein.

355. Finally, contrary to Mr. Anderson's assertion, my Opening Report sets forth numerous examples of devices (both electronic and non-electronic) that failed to achieve the desirable characteristics described above. *See* Lewis Opening Rep. § IX. It also provides extensive support for the proposition that electronic components have limited manufacturability, aesthetic, and/or ergonomic values. *See* Lewis Opening Rep. § IX. As I explain above, these desirable characteristics result from the combinations of elements recited in the Asserted Claims. *See supra* §§ VI.A.1.a.2; VI.A.1.b.4; VI.A.1.c.1. I therefore disagree with Mr. Anderson.

3. Industry Acceptance

356. In my Opening Report, I opined that Qvar® with dose counter's and ProAir® with dose counter's acceptance in the industry supported the non-obviousness of the Asserted

Claims. Although Mr. Anderson criticizes that analysis as "flawed," Anderson Rebuttal Rep. on Secondary Considerations ¶ 60; Anderson Opening Rep. ¶ 474, he fails to demonstrate any error in my opinions. I therefore disagree with Mr. Anderson.

357. First, Mr. Anderson repeats his assertion that the Teva-funded studies (Chipps 2017, Given 2012, and Kerwin 2017) are unreliable. *See* Anderson Rebuttal Rep. Objective Indica ¶ 60. I disagree. As I explain above, the fact that Teva funded these studies is neither uncommon nor evidence of their unreliability. *See supra* § VI.A.1.c.2.

358. Second, Mr. Anderson asserts that those studies show only that the "addition of a dose counter" is a secondary consideration of non-obviousness. *See* Anderson Rebuttal Rep. Objective Indica ¶ 60. Again, I disagree. As I explain in my Opening Report and repeat below, those studies specifically praised Qvar® HFA with dose counter and ProAir® HFA with dose counter. *See* Lewis Opening Rep. ¶ 481; Given 2012 ("ProAir HFA [p]MDI with the new integrated dose counter functioned reliably and accurately in the clinical setting."); Chipps 2017, TEVADOC-00000008, at -08 ("In patients with asthma and/or COPD, albuterol inhalation aerosol (ProAir HFA) with dose counter, compared with the same product without dose counter, had significantly lower healthcare resource use including all-cause and respiratory-related inpatient [emergency department] visits, higher refill rates, and fewer exacerbations."); Kerwin 2017, TEVADOC-00000412 ("In a real-world setting, asthma patients using ProAir HFA with [dose counter] experienced significantly fewer hospitalizations and [emergency department] visits compared with patients using ProAir HFA without [dose counter.]").

359. [redacted]

[redacted]

360. Finally, Mr. Anderson states that FDA's approval of Qvar® HFA with dose counter and ProAir® HFA with dose counter does not evidence non-obviousness because, if it did, "any inhaler with a dose counter that receives FDA approval (which comprises most inhalers sold in the U.S. in the last 15 years) is accepted by the industry." Anderson Rebuttal Rep. Objective Indica ¶ 61; Anderson Opening Rep. ¶ 474 ("The FDA has approved numerous dose counters."). Mr. Anderson mischaracterizes my opinions. In my Opening Report, I did not testify that Qvar® HFA with dose counter and ProAir® HFA with dose counter were non-obviousness just because they received industry approval. Rather, as I explained, FDA's approval of those devices is one indicator in favor of their non-obviousness, which is further confirmed with my conversations with others in the industry.

4. Praise

361. Mr. Anderson opines that the industry praise regarding Qvar® HFA with dose

counter and ProAir® HFA with dose counter that I discuss in my Opening Report does not evidence non-obviousness. *See* Anderson Opening Rep. ¶ 62. Mr. Anderson is incorrect.

362. As an initial matter, Mr. Anderson's criticisms of the Teva-funded studies cited in my report (Chipps 2017, Given 2012, and Kerwin 2017), is misplaced. *See* Anderson Rebuttal Rep. Objective Indica ¶ 62. As I explain above, the fact that Teva funded these studies is neither uncommon nor evidence of their unreliability. *See supra* § VI.A.1.c.2.

363. [redacted]

5. Copying

364. In my Opening Report, I opined that Cipla's and Aurobindo's copying the claimed inventions in the Asserted Patents supports the non-obviousness of the Asserted Claims. *See* Lewis Opening Rep. § IX.E. Mr. Anderson fails to demonstrate an error in this opinion. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 63; Anderson Opening Rep. ¶ 476.

365. First, Mr. Anderson asserts that I did not identify any documents or testimony supporting copying. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 63. Mr. Anderson is incorrect. *See* Lewis Opening Reps. § VIII.

366. Second, Mr. Anderson repeats his assertion that "that Cipla's ANDA Product utilizes the device describes in the prior art '406 Publication." Anderson Rebuttal Rep. on Secondary Considerations ¶ 63; Anderson Opening Rep. ¶ 476 ("I understand that Defendants use a dose counter disclosed in the '406 Publication, which predates the Asserted Patents."). As I explain in my Rebuttal Report and above, the dose counter disclosed in the '406 Publication is

not the same dose counter that is used in Cipla's and Aurobindo's ANDA Products. *See* Lewis Rebuttal Rep. §§ IV.A, VI. I incorporate that analysis as though fully set forth herein. (I address Mr. Anderson's assertions regarding Aurobindo's ANDA Product in my co-served report.)

367. Third, Mr. Anderson opines that the testimony of Mr. Walsh confirms that Cipla and Aurobindo did not copy the claimed inventions in the Asserted Patents. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 63. I disagree. While Mr. Walsh testified that he has not "come across a dose counter that's a copy of the one Teva uses," his testimony does not indicate that Aurobindo's and Cipla's ANDA Products do not infringe the Asserted Claims. Indeed, Mr. Anderson fails to identify any evidence that Mr. Walsh was aware of the devices used in Aurobindo's and Cipla's ANDA Products. Thus, Mr. Walsh's testimony does not support his conclusion.

368. Finally, Mr. Anderson states that "rel[ying] on the filing of Defendants' ANDAs as evidence of copying . . . is not compelling evidence of nonobviousness." Anderson Rebuttal Rep. on Secondary Considerations ¶ 64 (citing cases). While that may be correct as a general matter, in my Opening Report, I explained why, in this particular case, Defendants' copying provided especially compelling evidence. To wit, Defendants "had the opportunity to select a number of different inhalers and counter designs, including a number of different combinations of components, features, and configurations," but nevertheless "chose to select the same components, features, and configurations as those recited in the Asserted Claims or their equivalents." Lewis Opening Rep. § IX.E. Indeed, as set forth in my Opening Report, "Cipla chose to add a dose counter to its product based on Teva's announcement that it had added a dose counter to Qvar® HFA. That further evidences that the claimed inventions would not have been obvious." Lewis Opening Rep. § IX.E.

Dated: July 12, 2022

Dr. David Lewis. Ph.D.